Can Regulatory Efforts Motivate Innovation? The Case of Ventilator Innovations During COVID

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Abstract—In 2020, the United States Food and Drug Administration enacted the Emergency Use Authorization (EUA) to help respond to the COVID-19 pandemic. This regulatory pathway allowed for alternative uses of the existing medical devices and temporary authorization of new medical device designs, including ventilators. Given that regulation is often seen as a barrier to innovation, looking at ventilator innovation under the EUA is a good case study to explore if reducing regulatory barriers leads to increased or different forms of innovation. In this article, publicly available data are used to track the nature of innovation across all forms of ventilators submitted under the EUA pathway. We found that the EUA encouraged innovation in the ventilator industry, as indicated by new entrants to the medical device industry, a shift in the types of ventilators submitted for approval, and a wide variety of innovations. It also promoted new management practices to facilitate innovation, such as frugal design, a broader range of collaboration, and the use of open-source designs; these practices can be more widely used by industry to reduce costs, increase innovation, and serve traditionally underserved markets.

Key words: COVID, Food and Drug Administration (FDA), government, innovation, medical device, regulation, ventilator

I. INTRODUCTION

While regulation can be used to spur innovation, the impact of regulation can vary depending on the industry, form of government intervention, and focus of this intervention. Comprehensive understanding of the impact of government policy on innovation is essential, yet most research in this area focuses on pharmaceuticals or biotechnology. For the research that does focus on medical devices in particular, regulation is commonly framed as one of the largest barriers to innovation [Bergsland et al., 2014; Warty et al., 2021]. Given this barrier, and evidence that there has been a decline in the rate of innovation at the industry level [Bayon et al., 2016], it is important to understand how both firms and government can encourage medical device innovation.

Barriers to innovation during public health crisis, such as the COVID-19 pandemic, are particularly problematic when any delay in innovation could result in significant loss of life. For such emergencies—in the United States—the Emergency Use Authorization (EUA) pathway was created to promote the development and availability of specific medical devices and products during national emergencies [FDA EUA, 2017]. Although the timeline for authorization is not explicitly stated, the preparation and review time is significantly shorter than for more traditional regulatory pathways. Thus, the EUA provides an opportunity to look at innovation under less stringent regulatory regimes. By looking at changes in the nature and patterns of innovation during the EUA, we can better understand the amount and types of
innovation we may be missing under more stringent regulatory pathways, as well as highlight management and policy practices that can be used to increase innovation under other regulatory pathways.

This EUA process was instituted for a number of medical devices during the COVID-19 pandemic. COVID-19 is a respiratory disease that has severe short and long-term impacts on the breathing capabilities of those who contract the disease. Patients who experience severe symptoms often need a ventilator’s assistance to ensure proper exchange of oxygen and carbon dioxide into and out of the body. Ventilators have been in high demand since the beginning of the pandemic, and many countries are experiencing severe shortage of ventilators [Kliff et al., 2020; Wells et al., 2020]. In addition to availability, cost and use conditions of ventilators were also an issue of concern. Intensive care ventilators can cost as much as $50,000 and are complex machines with thousands of components that require highly trained professionals to operate. To help address issues of cost and availability, the United States Food and Drug Administration (FDA) enacted the EUA for ventilators.

Given that regulation is often seen as a barrier to innovation, looking at ventilator innovation under the EUA is a good case study to explore to determine if lifting regulatory stringency leads to increased or different forms of innovation. In this article, we will take a detailed look at the nature of ventilator innovation under the COVID EUA. Specifically, we use publicly available data to track the nature of innovation across all forms of ventilators submitted under the EUA pathway. We compare patterns in these innovations to ventilators approved under the normal 510(k) pathway for lower risk medical devices. After a brief review of the literature, we will outline our methods for data collection and analysis. Then, we will present our findings on the types of innovations presented in ventilators submitted under the EUA and conclude with implications for research and practice.

II. BACKGROUND

Innovation in Medical Devices  Innovation in the medical device industry is crucial to both improving existing and creating novel solutions. In the literature, the most common impacts on medical device innovation mentioned are regulatory processes, firm size, academia and industry, and pricing. One major deterrent to medical device innovation is the required regulatory processes [Warty et al., 2021; Bayon et al., 2016; Krucoff et al., 2012]. In addition to regulatory compliance decreasing the pace and increasing the cost of innovation, companies also point to the unpredictability of the regulatory process as a major deterrent. Unpredictability makes firms hesitant to introduce new products as they do not know how long it will take to get a return on their investment [Krucoff et al., 2012].

Additionally, some researchers point to the conservative nature of medical device companies, as well as those in healthcare. Approval time for new and innovative devices is significantly longer than if substantial equivalence to predicate devices can be claimed, allowing the use of the 510(k) pathway, an expedited regulatory pathway for lower risk medical devices that allows the safety of the device to be determined based on a predicate device rather than clinical testing [FDA Pathway to Approval, 2018]. Interestingly, although the 510(k) pathway was designed to reduce regulatory barriers to innovation, Bergsland et al. [2014] argue that the 510(k) pathway may inhibit innovation. It creates a disincentive to be the first firm to create a new product and companies choose to pursue “me too” products more often as the process is less burdensome; a novel claim is simply not worth the regulatory risk for many firms [Bayon et al., 2016].

These types of barriers are particularly important since smaller companies are more likely to pursue early stage innovation and produce novel products for needs in the market that have not been met, and often limited resources to put toward regulatory compliance [Roberts, 1988]. When larger companies do innovate, they typically focus on the end of the development process, such as improving existing devices rather than producing new ones. High costs and complicated processes associated with regulatory compliance also make it difficult for universities, which are an additional source of early stage innovation, to pursue approval for novel devices on their own [Bergsland et al., 2014].

Some studies have investigated how the pandemic has sparked innovative responses and provided learning opportunities for the medical device industry. These studies, however, primarily consist of anecdotal examples and do not focus on the EUA process itself, which is a critical regulatory response in national emergencies. Thus, in this article, we will take a more comprehensive look at one particular technology, ventilators, which were approved through the EUA process.

Data collection consisted of two efforts. First, we gathered historical information on ventilators from the FDA. We downloaded 1) all the available 510(k)s from 1976 to August 2020; and 2) collected EUA ventilator information from the COVID-19 Emergency Use Authorizations for Medical Devices for devices authorized between March 24, 2020 and August 30, 2020.

Second, we collected data from secondary sources, such as news...
articles, company web pages, product brochures, and general web searches. Overall, we had 62 products in our sample. We completed a detailed analysis of each ventilator on the EUA list and developed a coding structure that summarized unique properties of EUA products, such as design, components, or supply, as well as similarities and differences in product designs.

III. RESULTS

Shift in Ventilator Innovation

Figure 1 shows the number of 510(k) submissions that were cleared per year from 1976 to August 2020. Overall, submissions have shown an increasing trend, but the steep decrease from 2012 to August 2020 is prominent.

In comparison, there were a total of 77 EUA ventilator authorizations over five months from March 24, 2020 to August, 2020. This number is considerable particularly because of the noted decrease in 510(k) starting in the early 2000s.

There was also a shift in the type of ventilator approved through the EUA. As shown in Figure 2, the most common ventilator products prior to COVID-19 were CBK (Ventilator, Continuous, Facility Use), BZD (Ventilator, Noncontinuous Respirator), and BSZ (Gas-Machine, Anesthesia). These products made up 36%, 31%, and 14% of the approved products from 1976 to August 2020, respectively. The most common products authorized under the COVID-19 EUA were BTL (Ventilator, Emergency, Powered Resuscitator) at 38%, MNT (Ventilator, Continuous, Minimal Ventilatory Support, Facility Use) at 29%, and CBK (Ventilator, Continuous, Facility Use) at 12%. Most notable was the increase in MNT (Ventilator, Continuous, Minimal Ventilatory Support) product codes, which comprise only 1.4% of the products cleared through the 510(k).

We coded the companies into two categories: New Entrants, which included organizations that appear to have been created after the COVID-19 pandemic and pre-existing nonmedical device organizations (i.e., NASA, Fitbit, Virgin Orbit), and Established Players—a pre-existing medical device company. There were 18 New Entrants (10 new organizations, 8 from other industries) and 38 Established Players. In total, 33 of the Established Players produced ventilators or respiratory-related products prior to the EUA. New Entrants mostly submitted emergency ventilators, BTL, whereas Established Players submitted a variety of product codes.

In total, 24 of the EUAs were for devices that already existed, but were either not approved in the United States, had a change in intended use, or had a change in the device itself (or a combination of these reasons). Four products (VG70 ventilator, Mindray SV300/SV600/SV800, Atlan A350 and Atlan A350 XL, Beijing Aeonmed Shangrila510S) were on the market prior to the EUA and did not seem to make any modifications to their devices or the device’s intended use. These devices, however, were approved for use only in other countries. Seven devices were both previously not approved in the United States and called for changes in the intended use. Five devices did have 510(k) clearance, but the EUA was necessary to allow the devices to be used to treat COVID-19 patients. The most common change in intended use involved supportive devices for people with restrictive lung disorders or obstructive sleep apnea. Eight devices were submitted through the EUA due to changes in the device itself. Modifications include the use of alternate components, maximizing efficiency, modifying a device, such as changing a continuous positive airway pressure machine (CPAP) into a ventilator, and adding a closed-circuit design with a bacterial filter to the device.

Design Goals

The nature of the COVID pandemic led to a unique set of design goals, which were quite common across companies who discussed them. The most common goals were to design ventilators that were portable, affordable, simple to
use, easy to maintain, minimal components, and were easy to manufacture. These goals were determined in response to the situation imposed by COVID-19. Some of the goals revolve around the usability of the devices. An example of this is from AutoMedX who stated, “the idea was to make something simple that could be easily deployed by medics in high-stress environments” [AutoMedX, 2020]. The other goals revolve around designing a simple device that allows for rapid, large-scale production. Philips is a company that had ventilators on the market prior to COVID-19, but they created a new ventilator for the EUA that was “designed for mass production” [Philips, 2020].

Cost was a significant driver of these new products; many manufacturers pointed to price ranges or estimated cost in reference to a traditional ventilator. A traditional ventilator costs between $25 000 and $50 000 [Glass, 2019]. The devices submitted by companies that were new to the ventilator market generally cost less. For example, the Beijing Aeonmed was originally approximately $50 000, but the device submitted to the EUA was $12 000–$15 000. Vayu, whose mission is to create disruptive healthcare solutions [Vayu, 2020], had a device with the lowest cost at $120. Many of New Players to the market introduced products that were $5000 or lower (e.g., AustinP51 from Air Boost, Apollo ABVM from Stewart & Stevenson Healthcare, and Coventor from the University of Minnesota Medical School). Companies who were already in the ventilator market typically did not mention prices in the secondary sources, whereas more than half of the New Entrants mentioned a price or price estimate.

Types of Innovation We identified four main types of innovation in products approved under the EUA: intended use, supply chain, manufacturing, and components technology. An overview of sources of innovation and innovative solutions can be seen in Figure 3. In total, 12 of the products changed the intended use of existing products, such as positive airway pressure (PAP) machines for sleep apnea, to treat COVID-19 patients. Producers of 17 of the products mentioned innovations in the supply chain, 15 innovations in manufacturing, and 45 products involved innovations in components and technology. A list of the products with associated innovations appears in the Appendix.

Components and Technology: The component and technology innovations can be split into two categories based on the nature of the innovation. The first category includes features that were used in ventilators before the EUA, but the features were added to a new product design; the second category includes features that are less common or unique to the ventilator industry. Two of the most common components that

![Figure 2](image-url)
were emphasized in the EUA devices were the addition of certain filters to breathing circuits such as high-efficiency particulate filters and the ability for the device to be powered by batteries. Four companies mentioned the addition of autoclavable valves.

Newer technologies and solutions were also introduced into ventilators. Six devices involved the introduction of a remote access system, which was implemented differently in each device, such as with the use of a removable tablet, remote control, and Wi-Fi access. ResMed mentioned that they had big plans in digital health prior to COVID-19 and the pandemic brought some of their innovations to surface earlier than expected [ResMed, 2020]. Four products focused on software to enhance the usability of the devices. These ranged from incorporating artificial intelligence (AI) to programmable computer logic that enables the device to self-calibrate.

Two products used innovative air processing technologies. Vayu created an innovative air blender that does not require a compressed air tank [Vayu, 2020]. Not only was Vayu’s solution innovative, but the approach they took was unique as well. Vayu designed their bCPAP device as a neonatal solution because 80% of the ventilators utilized in the NICU are full-service ventilators. With this solution, these full-service ventilators can be used to treat adults with COVID-19 [Vayu, 2020]. Two devices took a modular approach to their design, which allows parts to be swapped based on availability and location of use. Finally, ten products pursued an automated bag valve mask (BVM) design; all of these products were made by New Entrants.

Supply Chain:
Another area of innovation dominated by New Entrants in the ventilator market was supply chain innovation. New Entrants were the only organizations that sourced BVM for their products—a total of 10 products. These companies chose to utilize a component that would be readily available in a hospital due to the equipment shortage from COVID-19. Two of the companies utilized components that can be made with do-it-yourself techniques, such as three-dimensional (3-D) printing, metal stamping, and modifying consumer goods. Another common set of innovations involved sourcing parts from off-the-shelf and globally available components. On the other hand, established ventilator companies attempted to combat the component shortage by utilizing a partner’s supply network rather than changing parts in the product design.

Manufacturing:
Innovative manufacturing approaches were introduced by both New Entrants and Established Players. New Entrants were the only

![Image](image-url)
companies that mentioned designing for manufacturability. Companies mainly approached this by minimizing the number of components. Spiro Devices was one of the companies that took this approach, "like so many other measures granted EUA, this may not be an ideal replacement for FDA-approved equipment, but it is an innovative, scalable solution that could mean big differences in the level of care at overburdened healthcare facilities" [Etherington, 2020, p. 1]. Other approaches included redesigning an existing manufacturing facility and partnering with other companies.

Established Players tended to utilize partnerships. Some partnerships occurred between a medical device company and a nonmedical device company, such as VenTec Life Systems and General Motors or GE Healthcare and Ford. Additionally, companies reworked typical work routines. Dragerwerk commented on the approach they took, "We have agreed with our employees on innovative work organization and working time models. This gives us the necessary flexibility to respond to the high volume of orders" [Drager, 2020].

Partnerships and Collaboration: Figure 4 shows an overview of the various types of partnerships and collaborations that occurred for the EUAs. New Entrants tended to partner with organizations that could help with the design of the device, whereas Established Players more often partnered with other companies for manufacturing capabilities. Partners ranged from aero-systems, automobile companies, government, universities, hospitals, doctors, and even patients. These partnerships were motivated by the urgency of the pandemic and were sometimes facilitated by the FDA. As stated by someone at LifeMech, "it is interesting how this cross-platform collaboration, from people who have never really designed or worked on a medical device, leads to something innovative. I think this goes to prove that there are no limits to innovativeness, and you can actually do things differently. So, you have got an engineer in Germany working with somebody out of their garage in Northern California, and at the end of the day, we would just integrate that data together" [LifeMech, 2020].

Open-Source Designs: Another trend we saw with EUAs was the use of open-source designs (LifeMech A-VS, Coventor Adult Manual Resuscitator Compressor, VITAL Ventilator, Mechanical Ventilator Milano (MVM), and Apollo ABVM). All five of the open-source designs were submitted by New Entrants, perhaps signifying a different motivation focused on public good rather than profit for innovation during the crisis.

IV. DISCUSSION AND CONCLUSION

The COVID Pandemic brought unique healthcare challenges that spurred innovations in the ventilator market. First, there was a short supply of ventilators exacerbated by shipping delays that made it difficult to obtain parts from inside and outside the United States. This motivated companies to create designs with minimal components and to use alternative components over typical ventilator components. Companies also needed to increase production to match demand and do so at lower costs. Second, with more widespread use of ventilators by practitioners less familiar with the technology, companies needed to design ventilators that were highly usable; new designs needed to be as intuitive as possible to ensure ease of use for medical personnel. This included ventilators that were both portable and affordable.

Our research found that the EUA led to product, process, and organizational innovations. Through the EUA, there were 77 device authorizations within five months, which is equivalent to the 510(k) submissions that occurred over the prior four to five years. Innovation also tended to happen in product classes that had been more stagnant in the past. Before the EUA, CBK (Ventilator, Continuous, Facility Use)
and BZD (Ventilator, Noncontinuous Respirator) were the most common products being developed. Under EUA authorizations, the percentage of BTL (emergency ventilator) devices approved through the EUA rose, as they were typically less complicated and easier to develop in a time of emergency. We also found an increase of MNT (PAP devices) submit under the EUA as medical practitioners found that they could use them as a noninvasive means of ventilatory support.

We also found a significant presence of New Entrants into the ventilator markets. New Entrants—companies that started after COVID-19 and pre-existing nonmedical device companies, respectively—made up 25% of the EUA devices and 32% of companies that submitted products under the EUA. Throughout the analysis, some patterns were seen in the innovative measures pursued by New Entrants, which are summarized in Table 1.

These differences point to two important findings. First is that reduction of regulatory barriers encourages New Entrants to the medical device field, who are typically sources of more early stage innovation. EUA allowed these firms to enter the medical device industry and implement their innovative solutions with minimal costs associated with regulatory approval. These New Entrants also spur innovative solutions through the growing landscape of open-source designs. Developers of three EUA approved devices noted that they gained their inspiration from open-source devices.

Second, the COVID-19 EUA may have helped Established Players implement emerging technologies that would have taken longer to be approved otherwise, such as remote access. Remote access is an example of a technology that was capable of being implemented prior to COVID-19, but was likely not implemented due to the costs of attaining FDA approval. COVID-19 accelerated the use of this technology in the medical field and the EUA allowed it to be implemented quickly. Thus, there may be more incremental innovations from established ventilator companies that are being shelved due to regulatory barriers.

Finally, both sets of companies benefitted from new partnerships to access complementary assets and skills. For established companies, these were mostly related to manufacturing. For New Entrants, there was a wider range of needs being addressed along the product life cycle.

**Limitations** The largest limitation to this article is the use of publicly available data and analysis of public statements. The data available from the FDA for EUA authorizations were minimal and we could not analyze EUA submissions or see submissions that were denied or in progress. If this information is available at some point in the future, an additional analysis could be completed.

Due to the limited FDA information, the methods consisted of analyzing public statements and information on company’s web pages. When analyzing public statements, there is a risk that the statement may be limited in the amount of information provided. In addition, public statements are often carefully crafted by the firms to highlight specific information, not to reveal all information. As a result, there is likely important information missing from these public statements. However, given that we were interested in understanding what was novel about a new product, and this is the type of information that is often used in marketing or in public statements, it is likely that these statements did reflect to some degree the nature of the innovation in each product. In addition, the news media was interested in highlighting this innovation and thus solicited information in this area.

**Implications** Our findings have implications for policy and medical device companies. For policy, these

| Table 1. Main Differences Between New Entrants and Old Players. |
|-----------------------------------|
| **Innovation Type** | Established Players | New Entrants |
| Either no product changes (EUA used to access US market or changing intended use) or late-stage product development modifications to utilize alternative components due to supply shortages and to increase safety when treating a person with a viral disease (examples: added filters, battery power capabilities, and autoclavable parts) | Early-stage innovations including components, overall device design, and new technology (examples: Automated BVM and 3-D printed components) |
| **Open Source** | 0 companies | 5 companies |
| **Partnerships** | Primarily partnered with other companies that could help with manufacturing capabilities. Less common partnership contributions include funding and design. | More likely to partner with organizations that could help with the design of the device. Also, partnerships for funding, device testing, device manufacturing, and FDA approval facilitation. |
findings suggest that regulations may impede innovation, particularly for New Entrants to the medical device market. Besides the more obvious call for making the regulatory process less onerous, there may be other roles for government to encourage innovation as well. First, the government could play a more active role in promoting partnerships among universities, health practitioners, small firms, established medical device companies, and companies in other industries. Similarly, they could support opportunities for knowledge brokers to spur healthcare innovation to support this collaboration.

Second, there could be a role for policy makers to incentivize the development of open-source medical device design. In line with past studies that have argued for the promise of open innovation for the medical device industry [Chesbrough, 2020], we saw that open innovation fed into multiple products submit and approved under the EUA. Open innovation may be particularly important in areas of frugal innovation, where initial returns might be low. Frugal innovation is creative and resourceful innovation that allows for changes in the face of institutional and resource constraints [Harris et al., 2020]. Frugal innovation was central in many of the solutions utilized during a global pandemic. Companies were responding to the shortage of medical device supplies and components, reduced delivery and production capabilities, and the need for reduced costs to ensure hospitals could afford an adequate supply of ventilators.

Our findings also have important implications for medical device companies. First, many of the Established Players used the EUA to implement incremental changes to design, some of which led to lower costs and more supply chain stability. This observation suggests that there is a continuing need for medical device companies to adopt similar innovations across their device platforms. While product changes are often avoided to avoid the costs of regulatory approval, identifying opportunities for designing new products with lower cost and more readily available parts can help companies lower costs and build resilience, making them better prepared for emergencies, such as COVID.

There are additional benefits in employing these and other frugal design practices. Incorporating increased usability and accessibility into medical device designs can make products available to a wider variety of users, particularly those in underserved markets. Ventilators are often very expensive and require highly trained professionals to operate. The innovation we saw emerge from the COVID-19 EUA often involved frugal solutions that were easier to use, cost less, and could be used in various locations, making them a good option for underdeveloped communities. Making medical devices accessible to these markets would not only be an important public service but also lead to new long-term markets for their products.

The findings also point to the value of developing platforms for sharing open-source designs. While companies may be understandably reluctant to share designs, doing so may help spur innovation. Thus, participating in open-source sharing when possible could help the industry as a whole. In addition, it could help facilitate the new partnerships, like those that developed under the EUA. Finding ways to continue the types of partnerships that developed out of necessity under the pressure of the pandemic could be particularly important for encouraging New Entrants to the medical device industry, who are likely to be the source of more early stage innovations.

The EUA period opened an opportunity for us to study innovation during a period where regulatory requirements for authorization changed. It created a window an opportunity for innovators, from both established medical device companies and companies new to the market, to introduce a range of product, sourcing, and process innovations that may not have otherwise been brought to market. The number of products authorized under the short time span of the EUA is particularly important given the decrease in new product authorizations for ventilators since 2012. Some of the approved products clearly involve innovations, such as frugal design and integration of AI, which can provide economic and social benefits long after the EUA path is removed. The question remains if these innovations will be approved under the normal regulatory process and if innovators and policy makers can learn from the EUA experience to increase future medical device innovation.

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**APPENDIX**

See Table 2.
Table 2. Innovations Identified in EUA Approved Ventilator Products.

| Innovations Identified   | Filter | Battery | Auto-clavable Parts | Remote Access | Software | Auto BVM | Modular Design | Air Process. Tech. |
|--------------------------|--------|---------|---------------------|---------------|----------|---------|----------------|--------------------|
| Air Boost                | AustinPS1 | X | X |                        |            |         |                |                    |
| AMBULANC TECH. Co., Ltd.| Models 6000S, T5, T7 | | X |                        |            |         |                |                    |
| AutoMedX Inc.           | SAve II Series Ventilator | | X |                        |            |         |                |                    |
| AutoMedX Inc.           | SAve II (M50016, M50017) | | X |                        |            |         |                |                    |
| Beijing Aeromed Co., Ltd.| Vc70 ventilator | |              |              |          |        |                |                    |
| BMC Medical Co., Ltd.   | Y 30T | |              |              |          |        |                |                    |
| BMC Medical Co., Ltd.   | LUNA GPAP 25A-LG3700 | |              |              |          |        |                |                    |
| BMC Medical Co., Ltd.   | LUNA G3 BPA5/T-LG3800-G3 B30VT | |              |              |          |        |                |                    |
| Covidiem LLC            | Puritan Bennett S60 Ventilator System | | X |                        |            |         |                |                    |
| Elettronica             | MVM |      |                        |              |          |        |                | X                  |
| Enexor BioEnergy, LLC   | X-VENT Emergency Ventilator | | X |                        |            |         |                |                    |
| Fitbit                  | Fitbit Flow | |              |              |          |        |                |                    |
| GE Healthcare           | pNeuton Model A-E Ventilator | |              |              |          |        |                |                    |
| Hillrom                 | MetaNeb 4 | |              |              |          |        |                |                    |
| Incoba LLC              | Apogee | |              |              |          |        |                |                    |
| Innovytec               | Ventway Sparrow | | X |                        |            |         |                |                    |
| JUXIN MEDICAL           | JIXI H-100 | | X |                        |            |         |                |                    |
| Lanick Med Systems LLC  | Lyra x1 and Lyra x2 Ventilators | | X |                        |            |         |                |                    |
| LifeMech, Inc.          | LifeMech A-VS | |              |              |          |        |                |                    |
| MEKICS Co., Ltd.        | MTV1000 ventilator | | X |                        |            |         |                |                    |
| MICO Medical s.c.o.     | MICo Medical CoroVent | |              |              |          |        |                |                    |
| Nanotronics Imaging     | nHale BiPAP device | | X |                        |            |         |                |                    |
| NeoNatal Rescue, LLC    | AdultLife Pro Ventilator | | X |                        |            |         |                |                    |
| Origin Medical Devices Inc. | Panther S Model PSDLVENT | | X |                        |            |         |                |                    |
| Philips Respironics      | VX850 Ventilator | | X |                        |            |         |                |                    |
| Philips Respironics      | E30 ventilator | | X |                        |            |         |                |                    |
| PVA                     | PREVENT | | X |                        |            |         |                |                    |
| RESMED                  | Lumis 150 VPAP ST (Amended 4/17/20) | | X |                        |            |         |                |                    |
| RESMED                  | AirCurve ST (Amended 4/17/20)) | | X |                        |            |         |                |                    |
| RESMED                  | Flexo Bi-Level ST | | X |                        |            |         |                |                    |
| RESMED                  | GA ST | | X |                        |            |         |                |                    |
| Resvent                 | iBreeze PAP | |                       |              |          |        |                |                    |
| Sagicco USA, LLC        | V20 SAGICO SYSTEM | | X |                        |            |         |                |                    |
| SecondBreathe LLC       | Pneumatic Resuscitator | | X |                        |            |         |                |                    |
| Shenzhen Mindray Biomedical | Mindray SV300/Sv600/SV800 | | X |                        |            |         |                |                    |
| Electronics             | ventilators | |          |              |          |        |                |                    |
| Spiro Devices LLC       | Spiro Wave (Amended 6/8/20) | | X |                        |            |         |                |                    |
| Stewart & Stevenson Healthcare Tech. | Apollo ABVM | |     |                        |            |         |                |                    |
| U of Minn. and Boston Scientific Corp. | Coventor Adult Man. Resuscitator | | X |                        |            |         |                |                    |
| Umbulizer               | UMV-001 EUA | | X |                        |            |         |                |                    |
| Vayu Global Health Innovations | Vayu bCPAP | | X |                        |            |         |                |                    |
| VenTec Life Systems     | V-Pro Emergency Ventilator | | X |                        |            |         |                |                    |
| Vent-a-Now              | Venti-Now Resuscitator Model JM-P2020A | | X |                        |            |         |                |                    |
| Virgin Orbit            | Virgin Orbit Resuscitator (Amended 4/23/20) | | X |                        |            |         |                |                    |
| VORTRAN Medical Technology I, INC | VORTRAN CO2VENT with PEEP Valve | | X |                        |            |         |                |                    |
| Vytaire Medical, Inc.   | LTV2 model 2200 and LTV model 2150 | | X |                        |            |         |                |                    |
| World Ventilator Foundation | WorldVent Ventilator | | X |                        |            |         |                |                    |

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