FDA approves first assay differentiating types of HIV
Bio-Rad Laboratories (Hercules, Calif.) has received FDA approval for its Bio-Rad BioPlex 2200 HIV Ag-Ab assay, the first diagnostic test that differentiates between types of HIV infection. The test distinguishes between HIV-1 antibodies, HIV-2 antibodies, and HIV-1 p24 antigen in human serum or plasma specimens. The test allows results of antigen and antibody detection to be reported separately. In addition to distinguishing between HIV-1 and HIV-2 infection, the reporting of distinct results helps differentiate between acute and established HIV infection.

The new test can be used in adults, children ages 2 and older, and in pregnant women. The assay may also be used to screen organ donors for HIV-1 and HIV-2 when the blood specimen is collected while the donor’s heart is still beating.

The assay is not approved for use in screening blood or plasma donors except in urgent situations where traditional licensed blood donor screening tests are unavailable or impractical.

Antisnoring system receives FDA approval
InSleep Health (Weston, Fla.) received FDA approval for its Cloud9 Anti-Snoring System, approved to eliminate or reduce simple snoring in adults. Cloud9 is a prescription device for home use. The device uses continuous low air pressure and includes a sports-styled, novel air circuit and comfortable, lightweight nasal interface, which serves as the mask.

A clinical trial of the device demonstrated marked reductions, if not complete elimination, of snoring by low levels of continuous air pressure in habitual snorers without sleep apnea. The device will be commercially available in 2016.

Dual balloon system approved as nonsurgical weight-loss procedure
The FDA approved ReShape Medical’s (San Clemente, Calif.) ReShape Integrated Dual Balloon System, a first-of-its-kind nonsurgical weight-loss procedure for patients with mild-to-moderate obesity. The procedure provides a new option for adults with a body mass index of 30 to 40 and one or more obesity-related comorbid conditions who have not succeeded at diet and exercise alone and do not want or do not qualify for bariatric surgery. A clinical trial showed that patients who underwent the ReShape procedure lost 2.3 times as much weight as a control group who received diet and exercise coaching only.

The dual balloon is inserted in the stomach endoscopically and filled with sterile 0.9% sodium chloride (methylene blue is added to the solution as a visual indicator; when the balloon is deflated, the solution is released from the deflated balloon and the patient’s urine turns a blue-green color). The device does not change or alter the natural anatomy and remains in the stomach for 6 months. During this time, and for 6 months after it is removed, patients receive comprehensive counseling and support services that include frequent in-office coaching sessions.

Contraindications for the device include: patients with a history of gastrointestinal (GI) surgery with sequelae (such as obstruction, adhesions, or peritonitis), prior bariatric surgery, inflammatory disease of the GI tract, hiatal hernia, coagulopathy, those at risk for upper GI bleeding, patients who are not willing to participate in an established, medically supervised diet and behavior modification program, those with alcohol or drug addictions, patients who are taking aspirin, anti-inflammatory drugs, anticoagulants, or other gastric irritants, or women who currently are or may become pregnant or breastfeeding.

Next-generation “smart” stethoscope
The FDA has cleared Eko Core, a digital stethoscope designed by Eko Devices. Eko Core is a “next-generation” stethoscope—the only one on the market to wirelessly stream heart sounds to a HIPAA-compliant smartphone app. It is also the first to integrate heart sounds directly into the patient’s electronic health record (EHR).

Eko Core is also the only stethoscope available that enables clinicians to switch between analog and digital modes, according to company executives. The Bluetooth-connected mobile app, available on the Apple App Store, enables clinicians to view a heart sound waveform, save heart sounds directly to a patient’s EHR and securely collaborate with a cardiologist. DOI: 10.1097/01.NPR.0000472256.43950.ze

Product descriptions and claims are based on materials furnished by the manufacturer. No endorsement by The Nurse Practitioner is intended.