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Upgrades and peripherals dominate pack

Radiology remains mired in the regulatory doldrums. The number of products receiving 510(k) clearance in June was abysmal by any measure. Just 22 radiological products cleared the FDA that month, hardly better than the historically low total of 20 in May but in line with the 20 clearances awarded in June 2001. For the year, radiology manufacturers are well below par, having won just 129 clearances compared with 142 in the first six months of 2001. Of the 22 that cleared in June 2002, MRI and x-ray led the pack with five each. XR devices included a CR-based bone densitometry software package and a dental x-ray system. The other three clearances were notable—one was Siemens' Axiom Artis, a cardiac cath system that incorporates a digital flat-panel detector in place of an image intensifier. The company released the product in July (SCAN 7/24/02).

Also in the x-ray group is the latest iteration of GE's mobile x-ray system, dubbed the AMX-4 Plus, and a peripheral device for Fischer Imaging's MammoTest stereotactic needle biopsy system. This device, called Mammopath, is used to examine excised tissue. Through its application, the physician can verify that the tissue removed during biopsy with MammoTest is from the target lesion. Fischer contends that doing this verification in the same room as the biopsy enables cases to be completed faster, thus limiting the time the patient needs to spend in the doctor's office or clinic. Mammopath, which cleared the FDA June 13, also can potentially limit the number of patient recalls, according to the company.

Four of the five MR devices that passed the FDA in June are coils, while the fifth is a software upgrade. Nuclear medicine accounted for three clearances, two of which are workstations. The other was actually for two devices, both gamma cameras from Colorado-based Nuclear Cardiology Systems. The company won 510(k) clearance for its CardioSPECT SC and D90 systems, which both rely on sodium iodide detectors. The D90 features two detectors, whereas the SC camera has just one. The two systems, which are manufactured in Budapest, are capable of both planar and SPECT studies. The acquisition/processing computer onboard each new product is manufactured by Segami. Ultrasound had three new clearances. One is a needle guide accessory for an existing system. Two are scanners—one dedicated to ophthalmic imaging, the other to radiology and ob/gyn applications. Canadian manufacturer Ultrasonix Medical makes this product, the Ergosonix 500 Ultrasound Scanner. The device is a highly mobile, software-controlled system capable of 2D B-mode, M-mode, pulsed Doppler, and color flow, including amplitude Doppler. The system generates real-time compound and harmonic images. Linear, convex, and microconvex transducers operate over a 2 to 15-MHz frequency range. Transducers feature linear, curved, and intracavitary arrays. The new product, which was cleared June 13, is designed for use in general radiology as well as ob/gyn. It can handle abdominal, small parts, peripheral vascular, musculoskeletal, cephalic, small organ, transvaginal, transrectal, pediatric, fetal, and cardiac imaging.

In the past, radiotherapy has led other groups more often than not. This time around, the group could manage only an in vivo dosimetry device and an upgraded therapy planning system. Image management also had two clearances. Notable among these was a software package called Rex 1.0, which supports 2D and 3D reconstruction of CT images. The software allows real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and reports. Rex can drive two monitors, one for image viewing and the other for displaying reports. The software, which was developed by PointDx and cleared by the FDA June 27, runs on a PC platform and Windows 2000. It allows TCP/IP networking, is DICOM 3.0 compliant, and supports lossless image compression. Its virtual endoscopy capability features one-click access to lesions, real-time display of endoscopic views, and internal and external viewing of hollow structures.

Disclosures: