



Koning Corporation
5555 Oakbrook Pkwy,
Suite #640
Norcross Georgia, 30093

On October 24, 2017 Koning Corporation received FDA supplement clearance for its new and improved Koning Breast CT 1000. This supplement clearance signals that the new version of KBCT 1000 has completed all aspects of Pre-Market Approval (PMA) for medical devices. This came following multiple changes to the physical design of the original KBCT 1000 device. Input power was designed to be similar to mammography requirements and the table profile is lower to the floor for easier patient positioning. Table side touchscreen panels were also added for ease of use. Software enhancements were incorporated for easier use and workflow integration.

The KBCT 1000 is the first commercially available low dose, 3D breast CT scanner designed specifically to image the entire breast with a single 10 second scan without compressing the breast tissue. The system acquires the entire volume of breast tissue producing 'true' Isotropic 3D images allowing radiologist's to co-register data in multiple planes similar to whole body CT imaging. The KBCT 1000 system includes a biopsy device to enable 3D-guided breast biopsies at significantly lower radiation dose compared to stereotactic guided biopsy.

This multi-application system was designed to be a replacement technology combining the diagnostic work up and 3D guided biopsy procedures into one device. In addition, KBCT 1000 will introduce opportunities for physicians to direct contrast enhanced imaging for complex cases as needed.

In a September 2014 FDA Consumer Health Information "[3D Technologies Poised to Change How Doctors Diagnose Cancer](#)" FDA reported that thanks to the regulatory work being done by a team of scientists at FDA that soon, three-dimensional (3D) images in actual 3D might help your doctor find hidden tumors and better diagnose cancers. The article indicated that: for patients, the (breast CT) procedure is more comfortable than regular mammography because the breast isn't compressed. Also, there's less radiation exposure than during a CT exam of the entire chest because only the breast is exposed to X-rays. The (breast CT) images have less distortion than mammography, and the system is optimized to differentiate between the breast's soft tissue and cancer tissue. These images will be very different from 2D mammograms. They're truly 3D images of the entire breast from any orientation. You can scroll through the slices (up and down, left and right) and get a unique view of the breast like never before. It gives doctors tremendous freedom in how they look at the interior of the breast and evaluate its structures. It's almost like seeing the anatomy itself.

The KBCT 1000 received its original PMA approval in 2015.

Press Contact

info@koningcorporation.com

www.koningcorporation.com