Breast Cancer Imaging System Earns FDA Approval

A breast-cancer imaging system invented by a Medical Center professor and designed to diagnose complex cancers is moving into commercial production.

The system, designed by Ruola Ning, a professor in the Department of Imaging Sciences, received premarket approval from the U.S. Food and Drug Administration this winter.

The stringent approval process required extensive clinical study.

Ning, the president and founder of the

DIAGNOSTIC DEVICE: Ruola Ning (right) worked with Avice O'Connell of UR Medicine and other investigators to develop a new system for imaging breast cancer. The system was given FDA approval to begin commercialization.

Medical Center start-up Koning Corporation, began working on the system, called the Koning Breast CT, in a small lab at the Medical Center more than a decade ago.

Using cone beam CT technology—an imaging system that disperses x-rays in the shape of a large cone instead of in narrow beams—the new system can create 3-D images of the entire volume of a breast without compressing tissue the way traditional mammograms do.

A patient lies on her stomach on an ergonomic examination table as one breast at a time is suspended through an opening in the table. The cone-beam shaped radiation source is positioned beneath the table to avoid exposing the chest and torso to radiation.

The system creates clear, high-contrast images that are capable of characterizing suspicious tissue and highlighting very small lesions, which are sometimes more treatable.

While not intended to be used for breast cancer screening, or to replace mammography, the new system is designed to diagnose cancer in women who have signs or symptoms of the disease, or who have abnormal findings after a standard screening mammogram.

During clinical studies, Koning partnered with Avice O'Connell, the director of Women's Imaging at UR Medicine.

They were joined by investigators from Elizabeth Wende Breast Care in Rochester, the University of Massachusetts Medical School, and Emory University. ®

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