January 28, 2013 08:00 AM Eastern Time

Augmenix Receives FDA Clearance to Market Its TraceIT™ Tissue Marker

WALTHAM, Mass.--(BUSINESS WIRE)--Augmenix, Inc., an innovative medical technology company focused on utilizing hydrogel technology in the fields of tissue marking and radiation oncology, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its TraceIT Tissue Marker, an absorbable tissue marker visible under CT, MR, cone beam and ultrasound imaging modalities. TraceIT Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures. TraceIT hydrogel is intended to mark tissue for at least 3 months after injection.

Radiation oncologists often combine, or fuse, MR and CT images to improve dose planning accuracy. However, most markers do not have equally good visibility on both CT and MR, limiting their usefulness for image fusion. “The excellent dual CT and MR visibility of TraceIT hydrogel will simplify image fusion, allowing for improved soft tissue alignment, resulting in improved radiotherapy plan accuracy and may help with cone beam CT verification during image guided treatment,” said Josh Yamada, MD, Radiation Oncologist at Memorial Sloan-Kettering Cancer Center.

“We look forward to bringing this product to the US market, and to provide clinicians with a new tool that marks tissues for treatment”

TraceIT Tissue Marker is a synthetic hydrogel consisting primarily of water and iodinated cross-linked polyethylene glycol (PEG). Injectable through a fine needle, small hydrogel injections are clearly visible in the lung, breast, prostate and other tissues. The hydrogel remains stable and visible in tissue for three months, long enough for radiotherapy, and then is absorbed and cleared from the body.

“When used to mark tumors, other commercial markers create a permanent image artifact in areas of particular interest. Since TraceIT hydrogel absorbs, long term visibility of the site is not compromised,” said Patrick Kupelian, MD, Professor of Radiation Oncology at UCLA.

TraceIT Tissue Marker is the first absorbable tissue marker designed to be CT, MR and ultrasound visible. “We look forward to bringing this product to the US market, and to provide clinicians with a new tool that marks tissues for treatment,” said Amar Sawhney, PhD, Augmenix CEO. “TraceIT Tissue Marker extends our absorbable hydrogel portfolio and represents a significant contribution in the field of radiation oncology, along with SpaceOAR System which is under clinical evaluation in the United States,” Dr Sawhney said. SpaceOAR System is CE Mark approved and currently commercialized in select European markets for prevention of rectal injury during prostate cancer radiotherapy.

About Augmenix, Inc. (http://www.augmenix.com): Augmenix is a privately held company based in Waltham, MA, focused on the development and commercialization of radiation oncology products using its proprietary hydrogel technology. The company was founded in January, 2008 and is privately funded.

Contacts

Augmenix, Inc.
Patrick Campbell, 781-902-1630
General Manager
pcampbell@augmenix.com