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Business

FDA clears NinePoint imaging system

By **Robert Weisman** | GLOBE STAFF JANUARY 06, 2012

Cambridge start-up NinePoint Medical Inc. has received clearance from the Food and Drug Administration to sell a new high-resolution optical imaging device that uses technology licensed from Massachusetts General Hospital.

The approval, announced yesterday, means the venture-backed company can begin marketing its Nvision VLE Imaging System. But NinePoint's chief executive, Dr. Charles Carignan, said it will wait until next year so it can complete tests on how the equipment can be used most effectively in gastrointestinal imagery.

That will help it target a projected \$1.7 billion market sought after by three-year-old NinePoint and rivals in the emerging field of endomicroscopy, which enables doctors to see areas deep within tissue that were not visible in the past. The larger endoscopy market, which NinePoint plans to later target, is estimated at \$5 billion.

"To get this clearance and have it behind us is just a tremendous milestone," Carignan said. "We'll be expanding our footprint as we get ready to commercialize."

NinePoint, funded by Third Rock Ventures of Boston and Prospect Venture Partners of Palo Alto, Calif., licensed the intellectual property behind its imaging system from the Wellman Center for Photomedicine at Massachusetts General in 2010. The licensing deal, covering 155 patents, was the largest ever involving a medical device at the Harvard-affiliated teaching hospital. The parties did not disclose financial terms.

Nvision "is configured to image the entire organ," said Dr. Gary Tearney, professor of pathology at Harvard Medical School and associate director of the Wellman Center, where he invented the technology with Dr. Brett E. Bouma. "This is made possible by doing microscopy very rapidly. It's a whole new paradigm."

Initially, the system - it consists of a proprietary console and disposable optical probes -

will be marketed as a screening tool that will help guide doctors in evaluating tissue structure and taking biopsies by offering two-dimensional, cross-sectional, depth visualization of the inside of lungs, bladders, and other organs. Eventually, as the technology improves, it might replace the need for biopsies, Tearney said.

FDA officials gave the system clearance under its so-called 510(k) approval process, which is used for non-life-sustaining and nonimplantable devices. That process reduced the waiting time for a decision to 90 days from the 180 days used for other devices. Eventually, the company may seek to market the system in Europe and Asia.

NinePoint has 27 full-time employees at its Kendall Square office.

Carignan, a former chief medical officer for endosurgery at Natick-based Boston Scientific Corp., said the company plans to hire 20 people this year - mostly engineers, scientists, and marketers - and expects to have 70 to 75 on staff by 2014. The optical system will be manufactured in the Boston area, he said.

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