FDA Approves New Robotic-Guided Surgical Implants

Mazor Robotics Ltd., a developer of surgical robotic systems and complementary products, announced today that it has received approval from the U.S. Food and Drug Administration (FDA) for the marketing of Emerald, their guided-surgical implant system for spinal fixation procedures. Mazor's flagship product, SpineAssist, is a surgical robotic system that enables surgeons to conduct spine surgeries in a safer and more accurate manner.

The system consists of a robot that is mounted on the spine during surgery and a workstation that runs advanced surgical planning software. Emerald implants are used to fixate vertebrae in multiple spine procedures (over half a million such procedures occur in the U.S. annually). Payment for such implants in the U.S. is around $6,000-$8,000. "We are encouraged to receive FDA clearance for another one of our products, and we are confident that this new implant system will strengthen our position in the spinal surgery market," said Ori Hadomi, CEO of Mazor Robotics. "Emerald implants are specially designed to work with our robotic system, creating synergy with the SpineAssist, which facilitates the surgical procedure, benefiting both patients and surgeons."

The Emerald implant successfully met all of the bio-mechanical and regulatory compliance requirements of the FDA. Additionally, the implant has been developed with the support of leading surgeons in both the U.S. and Europe. Mazor expects to begin marketing Emerald in the second half of 2011.

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