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Sirtex Medical Announces Certification of SIR-Spheres® Y-90 Resin Microspheres According to Medical Device Regulation (EU) 2017/745 and European Launch of the Innovative SIROS™ Delivery System

Sirtex brings an innovative liver cancer treatment delivery system to Europe, enhancing options for physicians and their patients.

WOBURN, Mass. (September 16, 2024) – Sirtex Medical (“Sirtex”), a leading manufacturer of interventional treatment solutions, today announced that it has received certification according to Medical Device Regulation (EU) 2017/745 for SIR-Spheres® Y-90 resin microspheres and its delivery systems, paving the way for the European launch of the SIROS™ Delivery System.

The EU MDR places greater emphasis on patient safety measures, risk management, post-market surveillance, and comprehensive data collection for medical devices seeking European market access.

“Patient health and safety are always at the forefront of our work. That is why we are particularly proud to receive EU MDR certification for SIR-Spheres® Y-90 resin microspheres and its delivery systems, including SIROS™. This achievement underscores our commitment to delivering innovative products responsibly and ethically,” said Matt Schmidt, CEO of Sirtex Medical Inc. “With the expansion of SIROS™ outside of the U.S., interventional radiologists in Europe now have an additional option to support patients battling metastatic colorectal cancer (mCRC) and unresectable hepatocellular carcinoma (HCC). This milestone reflects the outstanding efforts of our team, the rapid growth of our business, and the groundbreaking interventional oncology solutions we have developed.”

The SIROS™ Delivery System offers an intuitive, visual, and adaptable solution for physicians to administer SIR-Spheres® to liver cancer patients. Its easy-to-use design along with controlled administration provides physicians confidence in the Y-90 delivery.

“As an interventional radiologist, I am excited about the future use of the SIROS™ Delivery System,” shared Professor Thomas Helmberger, Head of Department of Radiology, Neuroradiology, and Minimal-Invasive Therapy at München Klinik Bogenhausen in Munich, Germany. “This device has an intuitive design and a precise control that will facilitate the administration of SIR-Spheres® Y-90 resin microspheres, and I am looking forward to incorporating it into my practice.”

About SIR-Spheres® in Europe

SIR-Spheres® are medical devices used in selective internal radiation therapy (SIRT) and are indicated for the treatment of unresectable hepatocellular carcinoma (HCC) and unresectable metastatic liver tumors from primary colorectal cancer (mCRC) in patients refractory to or intolerant of chemotherapy.

For a complete listing of indications, contraindications, side effects, warnings, and precautions, please consult the Instructions for Use at www.sirtex.com/EU/.

About Sirtex

Sirtex is a global healthcare company with offices in the U.S., Australia, Europe, and Asia, dedicated to improving patients' quality of life and longevity through innovative, minimally invasive cancer and embolization therapies. Sirtex's current leading product, SIR-Spheres® Y-90 resin microspheres, offers targeted radiation therapy for liver cancer. For more information, visit www.sirtex.com.

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