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HITACHI secures FDA 510(k) Clearance for its system

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Hitachi and Hokkaido Gets FDA 510(k) Clearance for Real Time Image Gating Motion Management for its Proton Therapy System



Hitachi, Ltd. and Hokkaido University announced that it has obtained U.S. Food & Drug Administration (FDA) 510(k) clearance for the commercialization of "Real Time Image Gating System for Proton Beam Therapy Systems" (RGPT).

With this approval systems can be used in the United States to treat patients with cutting-edge motion management together with its advanced Spot Scanning irradiation technology.

Proton therapy is a painless treatment and the procedure has very few side effects compared with that of traditional radiotherapy.

Jointly developed with Hokkaido University Hospital (Dr. Kiyohiro Houkin, Director) and its Clinical Research and Medical Innovation Center (Dr. Norihiro Sato, General Manager), RGPT has been used in approximately 70% of patients treated in the past 3 (approx.) years at the hospital.

RGPT has since been highly acclaimed and has been awarded the Imperial Invention Prize of 2017 - an honor bestowed by the Japan Institute of Invention and Innovation for the most outstanding inventions.

With this FDA clearance, Hitachi will move forward with plans to install RGPT at facilities under construction in the United States.

Hitachi provides superior proton therapy systems to world-class hospitals in Japan, the United States and around the world.

With more than 16,000 patients treated with its systems, Hitachi has earned a reputation for high reliability and achievements.

With its cutting-edge R&D, Hitachi will focus on the growing global demand for single room treatment facilities within the expanding market.

Hitachi and Hokkaido University will continue to accelerate innovation in particle therapy in order to contribute to cancer treatment around the world.