DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 17, 2016

Sumitomo Heavy Industries, Ltd.
% Cynthia Nolte, Ph.D., RAC
Senior Director, Regulatory Affairs
ICON Clinical Research LCC
62 Forest Street, Suite 300
MARLBOROUGH MA 01752

Re: K160612
Trade/Device Name: Sumitomo Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: August 3, 2016
Received: August 4, 2016

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# 4. INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Indications for Use**

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160612

Device Name
Sumitomo Proton Therapy System

Indications for Use *(Describe)*
The Sumitomo Proton Therapy System is a medical device designed to produce and deliver a proton beam for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**FORM FDA 3881 (1/14)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

# 510(K) SUMMARY
# Sumitomo Heavy Industries, Ltd.
# Sumitomo Proton Therapy System
# (per 21CFR 807.92)

## 1. SUBMITTER/510(K) HOLDER

Sumitomo Heavy Industries, Ltd.
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Date Prepared: June 27, 2016

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Sumitomo Proton Therapy System |
| Common Name: | Proton therapy system |
| Classification Name: | Medical charged-particle radiation therapy system |
| Classification Regulation: | 21 CFR 892.5050 |
| Product Code: | LHN |

## 3. PREDICATE DEVICE

- Sumitomo Proton Therapy System, Sumitomo Heavy Industries, Ltd. (K130426)
- IBA Proton Therapy System- Proteus 235, Ion Beam Applications, S.A. (K082416)

## 4. DEVICE DESCRIPTION

The Sumitomo Proton Therapy System (PTS) is a large-scale medical electrical system that consists of an integrated system of medical electrical equipment and non-medical electrical components to provide proton beam radiation therapy. The Sumitomo PTS consists of a 230 MeV Cyclotron, an Energy Selection System, a Beam Transport System, and a Gantry Treatment System. The new Sumitomo PTS is a modification of the Sumitomo PTS cleared for marketing under K130426 in November 2013. The purpose of the current 510(k) premarket notification is to add the pencil beam scanning functionality to the cleared Sumitomo PTS. The pencil beam scanning function allows for precise treatment of complex cancers, such as tumors located near critical structures and tumors with special shapes, including multi-site targets, without the need for beam shaping devices such as collimators or compensators. The pencil beam scanning function also produces a radiation field directly from the beam scan path layer by layer, which shortens

the treatment duration.

## 5. INDICATION FOR USE/INTENDED USE

The Sumitomo Proton Therapy System is a medical device designed to produce and deliver a proton beam for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

## 6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The Sumitomo PTS with pencil beam scanning and predicate Sumitomo PTS are identical except for the pencil beam scanning functionality. The major features of both the new device and the predicate Sumitomo PTS include:

- Cyclotron (230 MeV)
- Energy selection system (ESS)
- Beam transport system (BTS)
- Multipurpose Nozzle
- Respiratory Gating System
- Multi Leaf Collimator
- Online PET (Gamma ray detector)
- Compact Gantry
- Patient Positioning System

The operational characteristics of the new and predicate Sumitomo PTS are identical. The accelerator energies are in the same range (70 to 250 MeV). The beam transport systems are identical and deliver the accelerated protons to the gantries to be used for treatment in the same manner. The gantries are identical, and direct the radiation through treatment heads to patients in the same manner. The interface between the treatment planning software and the treatment heads, and the treatment planning software itself, are also identical.

The multi-purpose nozzle described in the current 510(k) premarket notification provides both wobbling and pencil beam scanning functions. The nozzle described in the original 510(k) for the predicate device was limited to the wobbling scanning function only. The user selects whether to use wobbling scanning or pencil beam scanning when planning for treatment.

In pencil beam scanning mode, proton beams delivered by the ESS, BTS, and GTS (Gantry Transport System) are irradiated to the isocenter without any scatter, focused by quadrupole magnets installed at the entrance of the nozzle. The beam is scanned laterally in two orthogonal directions continuously, controlled by a pair of scanning magnets.

## 7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

A series of factory and on-site safety and performance studies were completed to assess the performance of the new Sumitomo PTS with pencil beam scanning. Testing was performed and documented to ensure the design outputs of the system and its components have met design specifications in a complete and verifiable manner. Testing was performed at the unit level, subsystem level at the factory and on-site, and system level on-site. The extensive factory testing and on-site testing demonstrates that the Sumitomo PTS with pencil beam scanning met all performance requirement specifications for hardware, software, and safety requirements for a proton therapy system. The Sumitomo PTS with pencil beam scanning met the requirements of all design specifications.

Sumitomo conducted a usability assessment of the Sumitomo PTS with pencil beam scanning. Study participants completed two simulated clinical treatment scenarios as well as tasks identified as essential and critical. The results confirmed that users can safely and effectively perform the activities involved in pencil beam scanning.

## 8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted in support of this 510(k) premarket notification.

## 9. SUMMARY OF OTHER INFORMATION

No other information is submitted in support of this 510(k) premarket notification.

## 10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information provided in this 510(k), Sumitomo believes that the new Sumitomo PTS with pencil beam scanning is substantially equivalent to the previously cleared Sumitomo PTS. The Sumitomo PTS with pencil beam scanning has the same intended use, similar design, principle of operation, and technological characteristics as the predicate device. The only difference between the Sumitomo PTS with pencil beam scanning and the predicate Sumitomo PTS is the addition of the pencil beam scanning function to the multi-purpose nozzle. The addition of the pencil beam scanning function raises no new issues of safety or effectiveness. The Sumitomo PTS with pencil beam scanning met all performance requirements with no usability issues. Thus, the Sumitomo PTS with pencil beam scanning is substantially equivalent to the predicate Sumitomo PTS.

The new device raises no new issues of safety and effectiveness. The non-clinical safety and performance testing performed demonstrates that the new device met all test specifications and is suitable for its intended use. The usability evaluation confirmed that users can safely and effectively use the new Sumitomo PTS for pencil beam scanning.

## Table 5-1. Side-by-Side Comparison of New and Predicate Sumitomo Proton Therapy Systems with Reference Device

| Characteristic | Sumitomo Proton Therapy System with Pencil Beam Scanning NEW | Sumitomo Proton Therapy System (K130426) PREDICATE | Proteus 235 Proton Therapy System (K082416) REFERENCE |
|---|---|---|---|
| Manufacturer | Sumitomo Heavy Industries, Ltd. | Sumitomo Heavy Industries, Ltd. | IBA |
| Indication for Use | The Sumitomo Proton Therapy System is a medical device designed to produce and deliver a proton beam for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. | The Sumitomo Proton Therapy System is a medical device designed to produce and deliver a proton beam for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. | The PTS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. |
| Accelerator Type | Cyclotron | Cyclotron | Cyclotron |
| Particle | Proton | Proton | Proton |
| Accelerator: Energy (MeV) | 70 – 230 continuous | 70 – 230 continuous | 70 – 230 continuous |
| Depth of penetration | 3 cm-32cm | 3cm - 32cm | 5cm - 28cm |
| Field Shaping System | Wobbling, Pencil Beam Scanning | Wobbling | Double and Single Scattering, Uniform Scanning, Pencil Beam Scanning |
| Dose Rate: (Gy/min) | For Wobbling<br>> 2 Gy/min (110 to 230 MeV)<br>> 0.5 Gy/min for 10 cm x 10 cm x 4 cm (SOBP) at 70 MeV<br>For pencil beam scanning functionality<br>> 2Gy/min/liter (>150 MeV)<br>> 2Gy/min/(10cmx10cmx4cm) (110MeV)<br>> 0.5 Gy/min/(10cmx10cmx4cm) (Max depth 5cm with snout degrader) | For Wobbling<br>> 2 Gy/min (110 to 230 MeV)<br>> 0.5 Gy/min for 10 cm x 10 cm x 4 cm (SOBP) at 70 MeV | > 2Gy/min. |
| Safety System | Hard-wired relay and programmable logic controller (PLC) based interlock systems | Hard-wired relay and programmable logic controller (PLC) based interlock systems | Hard-wired relay-based interlock system |
| Treatment Geometry | Isocentric gantry or fixed horizontal beam delivery | Isocentric gantry or fixed horizontal beam delivery | Isocentric gantry or fixed horizontal beam delivery |
| Proton Beam current stability | Stable (Cyclotron) | Stable (Cyclotron) | Stable (Cyclotron) |
| Proton beam time structure | CW beam | CW beam | CW (Continues Wave) beam |
| Respiratory gating for wobbling mode | Simple<br>(Respiratory gating+ Wobbling timing )<br>(Passive ridge filter) | Simple<br>(Respiratory gating+ Wobbling timing )<br>(Passive ridge filter) | Not simple<br>(Range modulator + Respiratory gating + Wobbling timing) |
| Pencil beam scanning | Line scanning + spot scanning | N/A | Line scanning + spot scanning |
| Gantry size | Short axis gantry (Similar to Loma Linda gantry) | Short axis gantry (Similar to Loma Linda gantry) | Long axis gantry |
| Delivery proton dose distribution measurement | Off line phantom measurement + On line PET measurement | Off line phantom measurement + On line PET measurement | Off line phantom measurement |
| Accessibility to the patient in gantry in case of emergency | Quick access<br>(Caterpillar floor) | Quick access<br>(Caterpillar floor) | Need time to access patient (in case nozzle is lower position) |

N/A: Not available