ProNova Solutions, LLC
% Mr. Adam Kuhn
Vice President of Quality Assurance and Regulatory Affairs
330 Pellissippi Place
MARYVILLE TN 37804

Re: K162246
Trade/Device Name: ProNova SC360 Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: October 31, 2016
Received: November 7, 2016

Dear Mr. Kuhn:

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,

[Signature]

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

Enclosure
Indications for Use

Device Name
ProNova SC360 Proton Therapy System

Indications for Use (Describe)
The SC360 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.*
The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
EXHIBIT 05.01

510(k) Summary

ProNova Solutions, LLC

SC360

Proton Therapy System
510(k) Summary
for the ProNova SC360
Proton Therapy System

1. **Submitter**
   ProNova Solutions, LLC
   330 Pellissippi Place
   Maryville, TN 37804
   USA

   Contact Person: Adam Kuhn, VP of Quality Assurance and Regulatory Affairs
   Telephone: (865) 862-4100
   Fax: (865) 862-4101
   Email: adam.kuhn@pronovasolutions.com

   Date Prepared: 8/5/2016

2. **Device Name**
   Proprietary Name: ProNova SC360 Proton Therapy System
   Common Name: proton therapy system
   Classification Name: System, Radiation Therapy, Charged-Particle, Medical (21 CFR 892.5050)
   Regulatory Class: II
   Product Code: LHN

3. **Predicate Device**
   Ion Beam Applications S.A (IBA) Proteus 235, K083058

   **Reference Device**
   Indiana University Cyclotron Facility’s Proton Therapy System, K062891

4. **Intended Use / Indications for Use**
   The SC360 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.
5. **Device Description**

Using a beam of protons, the SC360 is designed to accurately and safely deliver a prescribed dose to a Treatment Volume in a patient with a solid tumor or other disease susceptible to radiation. The SC360 includes a method to; 1) accelerate protons to a fixed energy; 2) vary the proton beam energy to adjust its range in the patient; 3) transport the protons; 4) deliver the dose; 5) image the patient using Cone Beam CT (CBCT) or planar images; 6) position the patient relative to the proton beam delivery; and 7) record the details of the dose delivery.

The functions of each treatment room of the SC360 are performed by six independent systems that may be described as the Beam Production System (BPS), the Beam Modification System (BMS), the Dose Delivery System (DDS), the Positioning System (POS), the Independent Safety System (ISS), and the Treatment Room Control System (TRCS). The primary user interface is presented by the TRCS where treatment workflow and clinical Quality Assurance activities may be controlled. Servicing is accomplished through Service Interfaces for each independent system. Access to the service interfaces may be through the TRCS or the individual system control computer, all accessible only by qualified service engineers.

In the SC360, the cyclotron and fixed energy portion of the beamline make up the BPS and are independent of the BMS, which degrades the beam energy and finally transports the protons to the DDS through either a fixed beamline or 360-degree rotating gantry beamline. The ISS monitors all safety related signals and uses a high confidence method to control beam admission into a Treatment Room.

In each Treatment Room, prior to patient setup and treatment, information from a treatment plan is downloaded to the SC360. Next, the patient is immobilized on a robotic couch and moved to a treatment position as specified in the treatment plan. Volumetric (or orthogonal planar) x-ray images are acquired using a couch-mounted CBCT imaging ring. These images are used to determine the current location/orientation of the Treatment Volume by comparing and aligning with reference images and regions of interest provided in the treatment plan. The couch position/orientation is adjusted to bring the treatment isocenter to beam isocenter (in the prescribed orientation). The proton beam is delivered to the Treatment Volume in accordance with the treatment plan. During irradiation, the DDS controls and monitors the dose delivered to each spot, the spot location, and the total dose delivered. Results are recorded and stored in a format compatible with an Oncology Information System (OIS).

6. **Technological Characteristics**

The components and devices used in the SC360 and the Proteus 235 are substantially equivalent. The cyclotron used in the SC360 is a nominal 230 MeV (235 MeV max energy) isochronous cyclotron similar to the one used by IBA in the Proteus 235 predicate device. Beam transport components are typical of all proton therapy systems consisting of quadrupole magnets, dipole bending magnets, combined horizontal and vertical corrector dipoles, vacuum system components, and beam diagnostic components used for automatic beam steering and beam quality checks. Proton range is set using an automatically adjustable range degrader.
The SC360 is capable of delivering beam at any angle through 360 degrees about the patient. Delivery of dose is accomplished with Pencil Beam Scanning (PBS) using a spot-by-spot delivery technique whereby the scanning magnet in the nozzle places the beam in the spot position as prescribed by the treatment plan. A CBCT is used to image the patient in 2D or 3D with the patient in treatment position. A robot with couch is used to move the patient and Target Volume into treatment position.

The design features unique to the SC360 are also substantially equivalent to the Proteus 235 features. These unique features include:

1. A fast switching dipole magnet to turn the beam from the BPS beamline into a (BMS) Treatment Room beamline.
2. Permanent magnet quadrupoles and dipoles on the fixed energy portion of the BPS and BMS to turn and focus the beam.
3. A Beryllium degrader to adjust the range of the protons.
4. Superconducting magnets in the gantry beamline to turn and focus the beam.
5. A combined-function scanning magnet used to deflect the proton beam into the Treatment Volume at a distance of about 2 meters from Isocenter.
6. A Cone Beam CT mounted on a Treatment Couch used exclusively for imaging and to aid in positioning.
7. Independent control systems for each Treatment Room.

These features, although unique, have substantially the same technological characteristics as in the Proteus 235.

7. **Substantial Equivalence**

The ProNova SC360, the Proteus 235, and the reference device have an essentially identical intended use and indications for use. Similarly, the SC360 and the Proteus 235 have substantially similar technological characteristics, including system configurations and functions. The unique design features of the SC360 do not present any new issues of safety or effectiveness.

Like its predicate device, the SC360 is a device designed to produce and deliver a proton beam for treatment of a patient. Using a beam of protons, it is intended to deliver a therapeutic dose of radiation for the treatment of localized tumors or other diseases susceptible to radiation.

The SC360, like its predicate device, is located in a facility with one or more patient treatment rooms. The SC360 can be configured with any combination of Fixed Beam and Gantry Treatment Rooms up to a total of four rooms. All configurations are also possible with the Proteus 235.

Beamlines with focusing and bending magnets are used in the SC360 and the predicate. The magnets used, whether room temperature electromagnet, permanent magnet, or superconducting magnet, result in identical beam handling characteristics and are therefore
substantially equivalent. The range of the proton beam in the patient is adjusted by a degrader with nearly identical performance.

Both have CBCT capability and a robot that is used to position the patient to align the Treatment Volume with the prescribed proton beam fluence. Both the SC360 and the Proteus 235 use Pencil Beam Scanning to deliver the dose to the patient.

Based on the information provided in this 510(k) submission along with the contents of previous submissions, we conclude that the ProNova SC360 Proton Therapy System (SC360) is substantially equivalent to the previously cleared IBA Proteus 235 (K083058) Proton Beam Therapy System.

8. Summary of Non-Clinical Performance Testing as Basis for Substantial Equivalence

Non-clinical performance testing was completed to assess the performance of the SC360 regarding Essential Performance and Safety Requirements.

Performance Testing included the following categories:
   A. “Intended Use - Essential Performance Requirements”
   B. “Patient Safety - Essential Performance Requirements”
   C. “Intended Use – Additional Requirements”
   D. “Product Labeling”

The performance testing verified the design outputs met the design specifications of the system and components. Based on the completed performance testing, the SC360 was found to meet the Essential Performance and Safety Requirements.

9. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was performed or required.

10. Conclusions Drawn from Non-Clinical and Clinical Testing

The proposed device raises no new issues of safety or effectiveness. The non-clinical safety and performance testing demonstrates that the proposed device is Substantially Equivalent to its legally marketed predicate device, and is suitable for its intended use.