Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: Jun. 8, 2013

2. Sponsor Identification

   Hyper Technology Incorporation
   3404 jones creek road Baton rouge, Louisiana 70816

   Establishment Registration Number: Not yet registered

   Contact Person: Eugene Ji
   Position: General Manager
   Tel: 225 753 3219
   Fax: 225 753 3219
   Email: grpstars@ yahoo.com

3. Submission Correspondent

   Ms. Diana Hong & Mr. Tarzan Wang
   Mid-Link Consulting Co., Ltd
   P.O. Box 120-119
   Shanghai, 200120, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: Hyper Source-unit Rotating Gamma System (SGS-I+)
Proposed Device Common Name: Gamma System

Regulatory Information
Classification Name: System, Radiation Therapy, Radionuclide;
Classification: II;
Product Code: IWB;
Regulation Number: 892.5750;
Review Panel: Radiology;

Intended Use Statement:
The Hyper Source-unit Rotating Gamma System (SGS-I+) is a teletherapy device indicated for use in stereotactic irradiation of intracranial structures.

5. Predicate Device Identification

510(k) Number: K102533
Predicate Device Name:Rotating Gamma System Infini™
Manufacturer:Measep Infini Medical Science Technology Development Co., Ltd.

6. Device Description

The Hyper Source-unit Rotating Gamma System (SGS-I+) consist of Main Mechanical System, Localization Device, Control System, Therapy Planning System (TPS) etc.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.
IEC60601-2-11 (1997)(2004), Amendment 1 - Medical electrical equipment - Part 2-11: Particular

requirements for the safety of gamma beam therapy equipment.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	**Proposed Device** Hyper Source-unit Rotating Gamma System (SGS-I+)	**Predicate Device** Rotating Gamma System Infini™
Product Code	IWB	SAME
Regulation No.	21 CFR 892.5750	SAME
Class	Class II	SAME
Intended Use	The Hyper Source-unit Rotating Gamma System (SGS-I+) is a teletherapy device indicated for use in stereotactic irradiation of intracranial structures.	SAME
Category	Rotational	SAME
Treatment Bed Movement	3-D movement	SAME
Collimator Diameter Sizes	Φ 4mm,Φ8 mm,Φ12 mm,Φ 16mm	SIMILAR
Number of Collimator Channels	152	SIMILAR
Target Positioning	Automated	SAME
Dose Distribution	Dose sculpturing through programmable arcs	SAME
Number of ^{60}Co Sources	38	SIMILAR
Initial Overall Loading Activity	10600 Ci/3.922x10^{14}Bq	SIMILAR
Focus Dose-rate at Initial Loading	≥ 3 Gy/min	SAME
Penumbra on Focal Plane	≤ 12 mm	SIMILAR
Independent Dual Timer Accuracy	±1s	SIMILAR
Source Body Zero Position Returning Error	0.01°	SIMILAR

Collimator Selection Time	1s	SIMILAR
Treatment Bed Travel	X =400 mm; Y= 1057 mm; Z=300 mm	SIMILAR
Treatment Bed Maximum Loading Capacity	135 kg	SIMILAR
Treatment Bed Linear Travel Error (X,Y and Z)	0.1mm	SIMILAR
Treatment Bed Traveling speed	X, Z: 600mm/min Y: 1000mm/min	SIMILAR
Radiological Accuracy	≤1.0 mm	SIMILAR
Overall Length	5656 mm	SIMILAR
Overall Width	4171 mm	SIMILAR
Overall Height	2943 mm	SIMILAR
Overall Weight	30 T	SIMILAR
Power Supply	AC 480V±10% / 60Hz	SIMILAR
Backup Power Supply	≥ 30 min	SAME

The proposed device, Hyper Source-unit Rotating Gamma System (SGS-I+), is determined to be Substantially Equivalent (SE) to the predicate device, Rotating Gamma System Infini™, in respect of safety and effectiveness.

Item K 37)

Submission includes the following analytical studies, including associated protocols and line data.

Comments:

Need to provide the data for the Precision/Reproducibility and Accuracy.

Response

We have supplemented the "Total positional precision and dose error test report" of proposed device, and which has been reviewed by the registered Clinical Medical Physicist, JB Yu Zhang, PhD, DABR.

Please refer to:
Exhibit #17 Total positional precision and dose error test

I wish the response could address all of your concerns. Please feel free to contact me if you have any further questions via email at info@mid-link.net or via fax at (240) 238-7587.

Best Regards,

Fu, Lee

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Enclosures

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

February 28, 2014

Hyper Technology, Inc.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
SHANGHAI 200120
CHINA

Re: K131777
Trade/Device Name: Hyper Source-unit Rotating Gamma System (SGS-1+)
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: November 27, 2013
Received: December 2, 2013

Dear Ms. Hong:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Michael O. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K131777

Device Name: Hyper Source-unit Rotating Gamma System (SGS-I+)

Indications for Use:

The Hyper Source-unit Rotating Gamma System (SGS-I+) is a teletherapy device indicated for use in stereotactic irradiation of intracranial structures.

☒ PRESCRIPTION USE (Part 21 CFR 801 Subpart D)	OR	☐ OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K131777

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