Hitachi Ltd.
% Takahiro Haruyama
President
Globizz Corporation
1411 W. 190th St., Suite 200
GARDENA CA 90248

October 27, 2017

Re: K172087
Trade/Device Name: SANGRAY
Regulatory Class: Unclassified
Product Code: MOT
Dated: September 26, 2017
Received: September 27, 2017

Dear Takahiro Haruyama:

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 (DICE) 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 (DICE) 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,

Robert Ochs

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172087

Device Name
SANGRAY

Indications for Use *(Describe)*
The SANGRAY is an x-ray irradiation system intended for use in the irradiation of blood and blood products packaged in transfusion bags to inactivate lymphocytes for the prevention of graft versus host disease (GVHD).

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.

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SECTION 6: 510(k) Summary

6.1 Submitter

Date Prepared: July 7, 2017

510(k) Owner/Applicant:
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6.2 Device Identification

Trade Name:	SANGRAY
Common Name:	Blood Irradiator
Review Panel:	Radiology
Classification Name:	Irradiator, Blood to Prevent Graft Versus Host Disease
Device Class:	Unclassified
Product Code:	MOT

6.3 Predicate Devices

Trade Name:	Rad Source X-ray Blood Irradiator, Model RS-3400
Manufacturer:	Rad Source Technologies, Inc.
Reference:	K082921

Trade Name:	Raycell X-ray Blood Irradiator
Manufacturer:	MDS Nordion
Reference:	K051065

6.4 Device Description

The X-ray irradiation system SANGRAY consists of a power supply (high-voltage generation unit), controller panel (console), and a shielded protection unit which contains two vertically opposed X-ray tube assemblies that generate X-ray beams. Blood products are placed into a tray and irradiated with the X-rays in a sample chamber. The system has a built-in dosimeter which measures the exposure dose in real time and ensures that the X-ray irradiation is stopped automatically when the preset dose is reached. If the power supply fails during the X-ray irradiation, the dosimeter keeps the integral dose value in memory, which allows the operator to continue the X-ray irradiation after power is recovered.

6.5 Indications for Use Statement

The SANGRAY is an x-ray irradiation system intended for use in the irradiation of blood and blood products packaged in transfusion bags to inactivate lymphocytes for the prevention of graft versus host disease (GVHD).

6.6 Comparison of Technological Characteristics

SANGRAY is substantially equivalent to the Rad Source X-ray Blood Irradiator, Model RS-3400 (K082921) and the Raycell™ X-ray Blood Irradiator (K051065). All three devices use X-rays to irradiate blood products to reduce the risk of Graft Versus Host Disease (GVHD) associated with transfusion. Both SANGRAY and RS-3400 have similar device specifications and bench testing, while SANGRAY and Raycell™ both use an irradiation method through which two opposing X-ray tubes deliver uniform irradiation.

Table 6-1: *Comparison of Subject and Predicate Devices*

Characteristic	Subject Device	Predicate Devices	
	SANGRAY	RS-3400	Raycell™
Irradiation Method	Two opposing X-ray tube assemblies	One X-ray tube emits radiation in a 360°	Two vertically opposed X-ray tubes.
X-ray Tube voltage	150 kV	150 kV	160 kV
X-ray Tube Current	30 mA	25 mA	Not stated on 510(k) submission
Measurement Method	Minimum Dose: 15 Gy	Central Dose: 25 Gy	Central Dose: 25 Gy
Dose Rate	5.7-7.9 Gy/min	7 Gy/min	5 Gy/min
Max/Min Dose Ratio	Less than 1:1.5	Less than 1:1.3	Less than 1:1.2
Radiation Safety	Pb shielding, interlocks	Pb shielding, interlocks	Pb shielding, interlocks
Radiation Leakage	Less than 1 µSv/h	Not stated on 510(k)	Less than 5 µSv/h
Federal Regulatory Environment	Requires 510(k). Must comply with 21 CFR 1020.40	Requires 510(k). Must comply with 21 CFR 1020.40	Requires 510(k). Must comply with 21 CFR 1020.40

6.7 Non-Clinical Performance Test Summary

Safety of SANGRAY is demonstrated through the conducted safety tests. SANGRAY is in compliance with the following safety standards:

- ANSI/AAMI ES 60601-1:2005+A2(R2012)+A1 (**Appendix I**)
- IEC 60601-1-2:2007 (**Appendix J**)

In addition, the results of the non-clinical performance tests demonstrate that SANGRAY is substantially equivalent to the predicate devices.

6.8 Clinical Performance Test Summary

None.

6.9 Statement of Substantial Equivalence

SANGRAY is substantially equivalent to the Rad Source X-ray Blood Irradiator, Model RS-3400 (K082921) and the Raycell™ X-ray Blood Irradiator (K051065). The subject and predicate devices are indicated for the X-ray irradiation of blood and blood products to reduce the risk of Graft Versus Host Disease associated with transfusion. In addition, SANGRAY and the predicate devices are similar in their operating principles and technological characteristics. Standardized performance testing, as well as differences between the devices, did not raise any new concerns regarding safety and effectiveness. The results of the non-clinical performance tests demonstrate that SANGRAY is substantially equivalent to the referenced predicate devices.