R3 X-Ray L.L.C
℅ Mr. Robert Hase
Owner
2730 E. Broadway Blvd., Suite 160
TUCSON AZ 85716

August 17, 2020

Re: K201177
Trade/Device Name: RadGil2 US
Regulatory Class: Unclassified
Product Code: MOT
Dated: July 12, 2020
Received: July 23, 2020

Dear Mr. Hase:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K201177

Device Name
RadGil2 US

Indications for Use *(Describe)*
RadGil2 US is an X-Ray irradiation device intended for use in the irradiation of blood and blood products packaged in transfusion bags to inactivate lymphocytes for the prevention of graft vs 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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510(k) SUMMARY

Date Summary Prepared	April 23, 2020
Submitted By/Contact Person	Robert Hase R3 X-Ray LLC +1 (520) 771-0882 2730 E Broadway STE 160 Tucson, AZ 85716 rhase@r3xray.com
Trade Name	RadGil2 US
Common Name	RadGil2 US
Classification Name:	Blood irradiators have not been classified
Legally Marketed Predicate Device	SANGRAY (K172087)
Device Class:	None
Product Code	MOT

Description
The RADGIL 2 US x-ray blood irradiator is for use in Hospitals, Medical Centers and blood banks. The RADGIL 2 US x-ray blood irradiator consists of one lead-shielded cabinet containing one monoblock with one X-ray tube inside, one irradiation chamber, one control electronics, one computer for data management and one operator controls panel for the X-ray settings. The RADGIL 2 US x-ray blood irradiator is designed to accommodate a rotating canister of approximately 2.5 litres, to accommodate up to six standard 300 mL blood bags provided the bags are not frozen and the blood bag tubing is not an obstruction. The RADGIL 2 US x-ray blood irradiator is capable of irradiating the blood products to a central dose of 30 Gy, granting a minimum dose >15 Gy and a maximum dose < 50 Gy as required by US clinics, hospitals and blood banks. The RADGIL 2 US has a lockable panel to ensure that only authorized personnel make adjustments.

Intended Use of Device
Radgil2 US is an X-Ray irradiation device intended for use in the irradiation of blood and blood products packaged in transfusion bags to inactivate lymphocytes for the prevention of graft vs host disease (GVHD).

Summary of Technological Characteristics
Radgil2 US is substantially equivalent to the SANGRAY Blood Irradiator (K172087). Both devices use X-rays to irradiate blood products to reduce the risk of Graft Versus Host Disease (GVHD) associated with transfusion. RadGil2 US has similar device specifications and bench testing to SANGRAY with he exception that SANGRAY uses two opposing X-Ray tube assemblies and RadGil2 US has one tube emitting radiation with a rotating canister.

Comparison of Subject and Predicate Devices

Characteristic	*Subject Device*	*Predicate Device*
	RadGil2 US	**SANGRAY**
Irradiation Method	One X-Ray Tube with a rotating canister	2 opposing X-Ray tube assemblies
X-Ray Tube Voltage	180-200 Kv	150Kv
X-Ray Tube Current	5-20 mA	30mA
Measurement Method	2-min exposure	Minimum Dose 15Gy
Dose Rate	Up to 6.0 Gy/min (measured at the centre of the canister)	5.7-7.9 Gy/min
Max/Min Dose Ratio	less than 1:1.5	Less than 1:1.5
Radiation Safety	Pb shielding, interlocks	Pb shielding, interlocks
Radiation Leakage	<1,0 µSv/ h – measured at 5 cm from any external point of the unit	Less than 1 µSv/h

Non-Clinical Performance Test Summary

- Base Standard(s): UL 61010-1, 3rd Edition, May 11, 2012, Revised April 29 2016, CAN/CSAC22.2 No. 61010-1-12, 3rd Edition, Revision dated April 29 2016
- Additional Standards: IEC 61010-2-091: 2012 (first Edition)
- 21 CFR 1020.40 Cabinet X-Ray Systems
- 21.CFR 1010 Performance Standards For Electronic Products: General

In addition, the results of the Non-Clinical Performance tests demonstrate substantial equivalence to predicate device.

Clinical Performance Test Summary

None

Statement of Substantial Equivalence

RadGil2 US is substantially equivalent to the SANGRAY (K172087). 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. In addition, the SANGRAY is similar in 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.