Best Theratronics Limited
Ms. Jessica Mayda
Quality Assurance Specialist
413 March Road
OTTAWA, K2K 0E4, ONTARIO CA

January 2, 2019

Re: K181737
Trade/Device Name: Raycell MK1
Regulatory Class: Unclassified
Product Code: MOT
Dated: November 28, 2018
Received: December 10, 2018

Dear Ms. Mayda

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. 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

510(k) Number: K181737

Device Name: Raycell MK1

Indications For Use:

To irradiate cellular blood products to inactivate T-lymphocytes in order to prevent Graft Versus Host Disease.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

510(k) SUMMARY

Date Summary Prepared	June 14, 2018
Submitted by	Best Theratronics 413 March Road Ottawa, Ontario K2K 0E4 Canada Tel. (613) 591-2100 Fax. (613) 592-5680
Contact Person	Mrs. Jessica Mayda Quality Assurance Specialist
Trade Name	Raycell Mk1
Common Name	Raycell X-Ray Blood Irradiator
Classification Name	Blood irradiators have not been classified
Legally Marketed Predicate Device	Raycell MK2 (K161324)
Device Classification	None
Product Code	MOT

Description of Device

The Raycell Mk1 x-ray blood irradiator consists of one cabinet containing one x-ray tube, one high-voltage power supply, one radiation shielding chamber, control electronics, an internal cooling system, two removable shielding access panels to the irradiation chamber, a touch-based Graphical User Interface, and additional operator controls. The operator places the blood products to be irradiated in the canister or syringe holder, opens the door, places the canister or syringe holder in the holder on the turntable, closes the door and indicates the irradiation cycle on the Graphical User Interface. The Operator then uses the Operator controls to start the irradiation cycle. The design of this device is substantially equivalent to the predicate device.

Intended Use of Device

To irradiate cellular blood products to inactivate T-lymphocytes in order to prevent Graft Versus Host Disease.

This is the same intended use as previously cleared for the Raycell MK2 X-ray Blood Irradiator, (K161324).

The intended use of the modified device, as described in the labeling, has not changed as a result of the modifications.

Summary of Technological Characteristics

The Raycell is substantially equivalent to the predicate device (K161324).

The change to the Raycell design is to simplify the predicate design and have only one x-ray source. The same x-ray tube and high voltage generator is used in the new Raycell unit, but at lower power (3.2 kW). The system has a self-contained water cooling system and a new control system with a graphical user interface.

Following is a list of changes to the new design:

Canister Size

The new device is available only in a 1.6L. The predicate device was available in a 3.5L or 2L configuration.

Shielded Irradiation Chamber

The new device uses a lead shielded chamber as did the predicate design. Access is provided to the chamber via a sliding door.

Sliding Door

A sliding drawer arrangement has been replaced with a sliding door. External radiation fields have been decreased and manufacturability aspects have been improved.

All electrical interlocks have been maintained including an electro-mechanical safety interlock which prevents operators from opening the sample door when x-rays are generated.

Mechanical Motion

The shielded chamber includes stepper motors and shafts to rotate and translate a graphite cradle and reflector respectively. Interlocks prevent the operator from opening the sample door when motion is occurring.

Self Contained Water Cooling system

The new MK1 uses a self contained water cooling system. This replaces the need for an external water supply.

Digital Traceability

As with the predicate device, optional digital traceability is available as a database to be used with the Raycell to eliminate the need for manually recording data and reducing human error. This consists of a bar code reader to record and store data from the blood bag and view it on the integrated touch screen. It is able to retrieve cycle times from the Raycell, which allows the user to keep a history of the radiation cycles completed. It has no impact on radiation times or dose delivered and is not useable as a stand-alone product.

It is not intended to determine the suitability of donors and/or the release of blood or blood components for transfusion or further manufacture.

It does not change the intended use of the previously cleared Raycell X-ray Blood Irradiator.

Safety & Effectiveness

The safety of the Raycell is equivalent or better than the predicate device.

In terms of safety, the Raycell is designed to comply with

- IEC 60601-1-2: Edition 4.0 2014-02 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (Appendix L)
- IEC 60601-1: Edition 3.1 2012-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (Appendix M)

The performance of the device was tested against a set of functional specifications in an environment that simulated, as much as possible, the actual operating environment. Validation testing demonstrated that the device is as safe and effective as the predicate device.