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

August 12, 2016

Best Theratronics Limited
% Mr. Mike de van der Schueren
Quality & Regulatory Manager
413 March Road
Ottawa, Ontario K2K 0E4
CANADA

Re: K161324
Trade/Device Name: Raycell Mk2
Regulation Number: None
Regulatory Class: Unclassified
Product Code: MOT
Dated: August 4, 2016
Received: August 8, 2016

Dear Mr. de van der Schueren:

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,

For

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161324

Device Name
Raycell Mk2

Indications for Use *(Describe)*

The Raycell X-ray Blood Irradiator is intended for use in the irradiation of blood and blood products (packaged in transfusion bags) to inactivate T-lymphocytes for the prevention of Graft Versus Host Disease according to applicable FDA, AABB, Health Canada, and European guidelines.

The Raycell X-ray Blood Irradiator is also intended for use in the irradiation of intra-operatively salvaged blood for cancer patients undergoing surgery to assist in the prevention of metastasis.

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.

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510(k) SUMMARY

Date Summary Prepared	May 6, 2016
Submitted by	Best Theratronics 413 March Road Ottawa, Ontario K2K 0E4 Canada Tel. (613) 591-2100 Fax. (613) 592-5680
Contact Person	Mr. Mike de van der Schueren Quality & Regulatory Manager
Trade Name	Raycell Mk2
Common Name	Raycell X-Ray Blood Irradiator
Classification Name	Blood irradiators have not been classified
Legally Marketed Predicate Device	Raycell (K051065)
Device Classification	None
Product Code	90 MOT

Description of Device

The Raycell is a self-contained shielded cabinet X-Ray Blood Irradiator. The device consists of a lead shielded chamber containing two vertically opposed x-ray tubes with provision for a sample canister holder between them, dual power supplies and a operator control panel. The operator places the blood products to be irradiated in the canister, opens the drawer, places the canister in the holder, closes the drawer and starts the irradiation cycle at the Operator Panel. The design of this device is substantially equivalent to the predicate device.

Intended Use of Device

The Raycell X-ray Blood Irradiator is intended for use in the irradiation of blood and blood products (packaged in transfusion bags) to inactivate T-lymphocytes for the prevention of Graft Versus Host Disease. This is the same intended use as previously cleared for the Raycell X-ray Blood Irradiator, (K051065).

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 (K051065).

The change to the Raycell design is to create a unit with increased capacity using the existing design. The same x-ray tubes and high voltage generators are used in the new Raycell unit, but at a 25% higher power (4kW instead of 3.2kW on the predicate). There are no changes to the control system software from the predicate design.

Following is a list of changes to the new design:

Canister Size

The new device is available in either a 3.5L sample canister configuration or a smaller 2L sample canister configuration. The predicate device was only available in a 1.5L configuration.

Sliding Drawer

A combination of a pivoting outer door and a hinged inner door was replaced by a sliding drawer arrangement. External radiation fields have been decreased and manufacturability aspects have been improved.

All electrical interlocks have been maintained. A new electro-mechanical safety interlock has been added, which prevents operators from opening the sample drawer when x-rays are generated. This was done to compensate for elimination of the outer door present in the previous design.

Shielded Irradiation Chamber

The volume inside the lead shielded chamber has increased to accommodate the 3.5L sample canister. The chamber has also been modified using the same lead shielding to improve manufacturability and access for service and maintenance. New access panels have been added and are interlocked electro-mechanically (same as predicate device). External radiation fields have decreased from the predicate design.

Digital Traceability

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 a separate touch screen computer. 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 3.0 2007-03 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (Appendix L)
- IEC 60601-1: Edition 3.0 2005 + CORR. 1 (2006) + CORR. 2 (2007) 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.