Xcision Medical Systems, LLC
% Daniel R. Plonski, RAC
Director, Regulatory Affairs & Quality Assurance
9176 Red Branch Road, Suite O
COLUMBIA MD 21045

December 22, 2017

Re: K172706
Trade/Device Name: GammaPod™ - Model A
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: November 22, 2017
Received: November 22, 2017

Dear Mr. Plonski:

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.

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.

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,

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)*
K172706

Device Name
GammaPod - Model A

Indications for Use *(Describe)*

GammaPod™ is a teletherapy device intended for use in the noninvasive stereotactic delivery of a radiation dose to a partial volume of the breast in conjunction with breast conserving treatment.

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
As Required by 21 CFR §807.92(c)

I. GENERAL INFORMATION

Date Prepared: December 14, 2017

Manufacturer: Xcision Medical Systems, LLC
9176 Red Branch Road, Suite O
Columbia, MD 21045

Contact Person: Daniel R. Plonski, RAC
Director, Regulatory Affairs and Quality Assurance
9176 Red Branch Road, Suite O
Columbia, MD 21045
PHONE: (443) 681-7468
FAX: (443) 445-9201

II. DEVICE NAME/CLASSIFICATION

Trade Name: GammaPod™

Common Name: Cobalt Teletherapy Device, Stereotactic Radiotherapy System

Classification Name: Radionuclide Radiation Therapy System

Product Code: IWB

Device Classification: 21 CFR 892.5750, Class II

III. PREDICATE DEVICE IDENTIFICATION

Predicate Device: Rotating Gamma System, Gamma ART-6000 (K060314) now marketed by American Radiosurgery, Inc.

IV. DEVICE DESCRIPTION

The GammaPod™ is a teletherapy device that uses rotating, multi-source Cobalt-60 gamma-ray emitting sources to noninvasively deliver a focal dose of radiation to a partial volume of a human breast of a patient in the prone position while sparing the surrounding normal tissues and structures.

The GammaPod system contains 4 main components:

i. GammaPod irradiation unit. The GammaPod irradiation unit consists of a round "pod" containing a hemispherical source carrier that holds multiple Co^{60} sources, a hemispherical dynamically changing collimator system (inside and concentric to the source carrier), a hemi-elliptical-sphere treatment space (inside the collimator) within which the breast is positioned for treatment and a treatment patient loader that lifts and rotates a patient positioned on a treatment couch from the standing to prone position above the round "pod". The couch contains a portal within which the breast immobilization cup is affixed. The irradiation unit is controlled by a computerized treatment control system.

ii. Imager loader system. An imaging couch design and operation, which are similar to the treatment couch, are intended to make the imaging geometry identical to the treatment geometry. A patient is lifted and rotated from a standing position to prone position for imaging while wearing a breast immobilization device, which is affixed through a portal in the imaging couch.

iii. Breast immobilization system. A vacuum-assisted breast cup is designed to reproducibly hold the breast in place and provide an accurate reference frame to match the tumor with the coordinate system of the irradiation unit. The cup consists of a rigid reusable outer cup with an imbedded stereotactic frame and a thin inner cup joined together by a silicone flange at the chest side. A mild negative pressure is applied between the inner and outer cups causing the skin of the breast to press against the inner cup, securing the breast in place.

iv. Treatment planning system. A treatment planning system is designed specifically for planning breast radiotherapy using the GammaPod by:

a) Placing the breast images within the stereotactic localization frame coordinate system through an image registration process;
b) Optimizing a dynamic and deliverable trajectory of the focal spots of different sizes to realize the prescribed dose to the target volume while minimizing radiation exposure to the surrounding tissues and structures; and
c) Ensuring accurate dose calculation of the optimized plan and providing dosimetric indices for review.

V. INTENDED USE

GammaPod™ is a teletherapy device intended for use in the noninvasive stereotactic delivery of a radiation dose to a partial volume of the breast in conjunction with breast conserving treatment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO THE PREDICATE DEVICE

The GammaPod physical design is fundamentally the same as the predicate Device, the Rotating Gamma System – Gamma ART-6000, which uses the same means of achieving a highly focused radiation dose at the isocenter (i.e., using multiple rotating Cobalt-60 sources to focus the radiation at the common isocenter). As compared with the Predicate Device, the GammaPod system has the same intended use, uses the same radioisotope, applies the same operating principle, has similar technical characteristics and meets similar performance specifications. Both the GammaPod and the Predicate Device meet the same sets of regulations and standards.

The key difference between the GammaPod and the Predicate Device is in the site of treatment. While the GammaPod is physically designed specifically for delivering a focal dose of radiation to a partial volume of the human breast, the Predicate Device is designed to treat intracranial lesions. Therefore, the orientation of the treatment space is different.

VII. STANDARDS APPLIED

- IEC 60601-1: 2012 (ed. 3.1): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 (ed. 4.0): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-4: 2000 (ed. 1.1): Medical electrical equipment – General requirements for safety – Collateral Standard: Programmable electrical medical systems
- IEC 60601-2-11: 2013 (ed. 3.0): Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment
- IEC 60731: 2016 (ed. 3.1): Consolidated Version Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy
- IEC 61217: 2011 (ed. 2.0): Radiotherapy equipment - Coordinates, movements, and scales
- IEC 62083: 2009 (ed. 2.0): Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

- IEC 62274: 2005 (First edition): Medical electrical equipment – Safety of radiotherapy record and verify systems
- IEC 62304: 2006: Medical device software - Software life cycle processes
- IEC 62366: 2016 (ed. 1.0): Medical devices –Part 1: Application of usability engineering to medical devices
- ISO 10993-1: 2009 (ed. 4.0): Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 14971: 2007 (Second edition): Medical Devices – Application of Risk Management and Medical Devices

VIII. SUMMARY OF NONCLINICAL TESTS

A Hazard Analysis was conducted for GammaPod according to ISO 14971 and methods for preventing such hazards were identified and verified. Verification and validation of the control system software and treatment planning system software were conducted in house in accordance to the established Verification and Validation (V&V) Protocols within FDA Software Validation guidance.

Radiation tests including radiation safety measures and radiation dosimetric accuracy tests were conducted to meet the requirements of the NRC and IEC 60601-2-11. The measured radiation leakage profile of the GammaPod is far below the recommended levels of IEC 60601-2-11 and NCRP Report #102 as shown in the Radiation Test Report.

Tests for mechanical safety and mechanical accuracy were also conducted in house. Additionally, a certified laboratory has evaluated GammaPod and certified its compliance with IEC 60601-1:2012 Edition 3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. EMC testing was conducted by the same lab showing that the GammaPod meets IEC 60601-1-2:2007 Edition 3.0 Medical electrical equipment- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Bio-compatibility has been verified to the requirements of ISO 10993 by a certified laboratory for the breast cup and the silicone flange.

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

These tests have demonstrated that the GammaPod system has met its specifications, demonstrated substantially equivalent performance to the predicate device and is suitable for its intended use.

IX. SUMMARY OF CLINICAL TESTS

Clinical testing was conducted through an FDA-approved Phase I clinical trial under IDE No. G120054. Seventeen (17) patients were enrolled from March, 2016 to August, 2017 according to the approved IDE clinical protocol. For each patient, the feasibility of using the GammaPod to deliver a focal dose of radiation to a partial volume of the breast while keeping the dose to other surrounding tissues and organs within specified limits was evaluated. For each patient, the safety and dosimetric accuracy were also evaluated and the results demonstrated that the GammaPod system can safely deliver the prescribed doses as intended.

X. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS

As compared with the Gamma ART-6000, the GammaPod system has the same intended use, uses the same radioisotope, applies the same operating principle, has similar technical characteristics and meets similar performance specifications. Both the GammaPod and the Predicate Device meet the same sets of regulations and standards. The mechanical design differences between the GammaPod and the Predicate Device do not raise any new or different issues of safety or effectiveness. The GammaPod is therefore substantially equivalent to the Predicate Device.