Akesis Inc
% Mr. Christopher Brown
Director Quality Assurance and Regulatory Affairs
5129 Commercial Circle
CONCORD CA 94520

February 4, 2020

Re: K200050
Trade/Device Name: Akesis Galaxy RTx
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: Class II
Product Code: IWB
Dated: January 8, 2020
Received: January 10, 2020

Dear Mr. Brown:

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)*
K200050

Device Name
Akesis Galaxy RTx

Indications for Use *(Describe)*
The Akesis Galaxy RTx Gamma System, is a teletherapy device intended for the stereotactic irradiation of human head structures.

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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Premarket Notification [510(k)] Summary
Akesis Galaxy Rotating Gamma System

The following information is provided following the format of 21 CFR 807.92.

I. GENERAL INFORMATION

Submitter's Name:	Akesis Inc. 5129 Commercial Circle Concord, CA 94520
Contact Name:	Christopher Brown Phone: +1 925 408 1381 Fax: +1 925 326 2646

Date Prepared:	January 08, 2020

II. DEVICE INFORMATION

Proprietary Name:	Akesis Galaxy RTx
Classification Name:	Radionuclide radiation therapy system
Device Classification:	21 CFR 892.5750
Device Class:	Class II
Product Code:	IWB
Common/Usual Name:	Radionuclide radiation therapy system

III. PREDICATE DEVICE Akesis Galaxy Rotating Gamma System (K190844)

IV. DEVICE DESCRIPTION

The Akesis Galaxy RTx, is a medical teletherapy device, which contains (30) Cobalt-60 sources, distributed in a single, compact source carrier or source drawer, which is inside a hemispheric shield. Immediately adjacent to the source unit is the "built-in" primary collimator. An independently rotating secondary collimator hemisphere contains 4 sizes of collimators and a blocking position.

The rotating gamma system focuses the thirty beams and combining their individual doses at the target. The design of the system automates the treatment delivery by moving the target to the focal point, while the patient's head is immobilized in a headframe which has been fitted prior to the commencement of treatment. The entire system consists of a) the y-ray treatment unit, and b) the stereotactic localization system.

V. INTENTDED USE	The Akesis Galaxy RTx Rotating Gamma System, is a teletherapy device intended for the stereotactic irradiation of human head structures
VI. INDICATIONS FOR USE	The Akesis Galaxy RTx Gamma System, is a teletherapy device intended for the stereotactic irradiation of human head structures

VII. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Akesis Galaxy RTx has the same intended use, uses the same radioisotope, applies the same operating principle, has the same technical characteristics and meets the same performance specifications. Both the predicate and the Akesis Galaxy RTx meet the same set of regulations and standards.

The following technological differences exists between the subject and the predicate device:

- Sources now contained in a single source drawer assembly rather than distributed in a hemisphere arrangement
- Treatment beam angle increased by 10 degrees relative to the vertical plane passing through isocenter
- Treatment table now supports increased weight limit (210kg)
- Reduced thickness treatment cavity doors due to increase in treatment cavity shielding

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence:

Biocompatibility Testing
In conformance with FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'", there was no change to biocompatibility compared to the predicate device due to the same patient-contact materials used in this medical device.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and electromagnetic compatibility (EMC) testing was conducted on this medical device. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC. Successful testing was performed in accordance with IEC standards 60601-1, 60601-2-11, 60601-1-2, 61217, 62274 and 62366.

Hardware and Software Verification and Validation Testing
Hardware and software verification and validation testing was conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards. Test results showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

Animal and Clinical Studies
Animal and clinical testing was not required.

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

IX. CONCLUSIONS

The Akesis Galaxy RTx has the same intended use, fundamental scientific technology and principles of operation as the predicate device.

Use of the Akesis Galaxy RTx does not raise any new or different issues of safety or effectiveness when compared with the predicate device.

Performance tests have demonstrated that the Akesis Galaxy RTx has met its specifications, demonstrated substantially equivalent performance to the predicate device and is suitable for its intended use.