May 14, 2021

Klarity Medical & Equipment (GZ) Co., Ltd.
℅ Mr. Peter Larson
President & CEO
Klarity Medical Products, LLC
600 Industrial Parkway
HEATH OH 43056

Re: K202747
Trade/Device Name: Klarity Bolus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: April 2, 2021
Received: April 7, 2021

Dear Mr. Larson:

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,

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)*
K202747

Device Name
Klarity Bolus

Indications for Use *(Describe)*

Klarity Bolus is indicated for radiation therapy clinical treatments as a tissue equivalent aid to correct for anatomical irregularities and deliver a prescribed dose to the skin and underlying tissue. Target population is Adult, Child and Infant, and Federal (USA) law restricts this device to sale by, or on the order of a physician.

Klarity Bolus has been tested for tissue equivalency at 6 MV and 10 MV photon and at 6 MeV and 12 MeV electron energy levels. Further testing will be required to confirm performance with proton therapy systems.

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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Submission K202747 – February 2, 2021

510(k) Summary

I. SUBMITTER

Submitter: Klarity Medical & Equipment Co., Ltd.
No. 14, 3rd Street Shawan, GETDD
Guangzhou 510730, China
Ph.: +86 (20) 8222-6380
Fax: +86 (20) 8208-8552

FDA Registration No. 3003803149

Contact Person Ms. Lucy Li
Director of International Sales
Klarity Medical & Equipment Co., Ltd.
Email: lucy@klarity-medical.com
ph. 86-20-82226380

Correspondent: Peter M Larson
President
Klarity Medical Products, LLC
Email: peter@klaritymedical.com
ph. 614-226-2640

II. DEVICE

Trade Name: Klarity Bolus

Common Name: Bolus Material for Radiation Therapy

Classification Name: System, Therapeutic, X-Ray (21 CFR 892.5050)

Product Code: IYE

Device Class: II

Regulation Number: 892.5050 Medical charged-particle radiation therapy system

III. PREDICATE DEVICE

Super Tissue – Bolus Material
510(k) – K993742

IV. DEVICE DESCRIPTION

Klarity Bolus is a moldable gel sheet material to be used by trained radiation therapy professionals as an aid to radiation treatment of uneven areas of a patient, such as at the nose or ears, to make up for

missing tissue, or to provide build-up of radiation dose to the skin surface. The use of bolus is decided by a doctor or professional on a case by case basis, deciding if bolus is needed or appropriate, and deciding the amount and shape of the bolus material to be used.

During radiation therapy treatments there can often be a "build up" of radiation dose a few millimeters beneath the surface of a patient's skin. Bolus material can be used to create a simulated layer of tissue that will raise the depth of the "build up" to be closer to actual skin level. This can benefit the accuracy and dose level for treating a skin cancer, for example. Bolus materials have been used for this purpose for many years.

Klarity Bolus is provided as a non-sterile 30x30cm sheet in various thicknesses from 0.5cm to 4cm. Klarity Bolus incorporates a thin mesh netting in the sheet to enhance dimensional stability and prevent easy tearing. In clinical use a therapist will use scissors to cut the sheet into a desired shape. Klarity Bolus is tacky and self-adherent, so it can be layered to a desired thickness. The shaped piece will be placed on the patient's skin in a chosen location, where it will adhere enough to stay in place but can be easily removed. Klarity Bolus has less tackiness than other bolus materials, a manufacturing choice made in response to clinician complaints about the oily and overly tacky surface of other bolus materials. Sheets are semi-transparent, allowing a therapist to see the underlying treatment area.

Klarity Bolus is for single patient use only, and can be discarded with normal hospital waste. For cleanliness reasons, gloves should be worn when working with bolus sheets.

Klarity Bolus has been tested for tissue equivalency at 6 MV and 10 MV photon and at 6 MeV and 12MeV electron energy levels. Results compare favorably with the predicate device and other bolus materials. Further testing will be required to confirm performance with proton therapy systems.

V. INDICATIONS FOR USE

Klarity Bolus is indicated for radiation therapy clinical treatments as a tissue equivalent aid to correct for anatomical irregularities and deliver a prescribed dose to the skin and underlying tissue. Target population is Adult, Child and Infant, and Federal (USA) law restricts this device to sale by, or on the order of a physician.

Klarity Bolus has been tested for tissue equivalency at 6 MV and 10 MV photon and at 6 MeV and 12 MeV electron energy levels. Further testing will be required to confirm performance with proton therapy systems.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are bolus materials of similar appearance. The following technical elements are the same for both devices:

- Intended use
- Indications for Use
- Size and shape of sheets offered for sale
- Semi-transparent, flexible sheets
- Sheets have tackiness
- Target population

- Anatomical Sites
- Where used (RT clinics)
- Human Factors
- Standards met (FDA registration and classification)
- Subject device has a measured density of 1.01/cm^3. Predicate device has a reported density of 1.03[3]. These are equivalent within a reasonable margin of measurement accuracy.
- Biocompatibility (same standards met)
- Compatibility with environment and other devices
- Sterility (both non-sterile)
- Electrical and Mechanical safety

Differing Characteristics are:

- Subject device incorporates a thin layer of mesh netting in the sheets to aid dimensional stability. Predicate device is a gel material only.
- Chemical formulations of the subject and predicate devices differ, but create devices with the same density, appearance and function.
- Subject device has slightly less tackiness than predicate device.
- Predicate device is sold with and without a "skin". The skin is a thin plastic barrier surrounding the sheet. It is sometimes preferred by therapists to block the tackiness of bolus materials. Subject device will be sold without a "skin", as the reduced tackiness renders it unnecessary.

VII. PERFORMANCE DATA

Biocompatibility testing of Klarity Bolus has been conducted in compliance with ISO 10993 standards, and is included with this submission:

- Attachment A: Cytotoxicity Test
- Attachment B: Skin Sensitization Test
- Attachment C: Skin Irritation Test

Klarity Bolus has been tested for tissue equivalency at 6 MV and 10 MV photon and at 6 MeV electron energy levels. Results are included with this submission. Further testing will be required to confirm performance at other electron energy levels and proton energy systems.

Element content has been tested and Zeff values confirmed according to Chinese standard JY/T 017-1996. Data is included with this submission.

VIII. CONCLUSIONS

Non-clinical data and bench testing support the safety and effectiveness of this device for its intended use. Klarity Bolus has been tested for tissue equivalency at 6 MV and 10 MV photon and at 6 MeV and 12 MeV electron energy levels. Further testing will be required to confirm performance with proton therapy systems.