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

November 15, 2016

IZI Medical Products LLC
% Mr. Qiang Cao
Manager of Quality Assurance and Regulatory Affairs
5 Easter Court Suite J
OWINGS MILLS MD 21117

Re: K162265
Trade/Device Name: CushionCast™ Moldable Cushion
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 29, 2016
Received: October 4, 2016

Dear Mr. Cao:

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 on last page.

510(k) Number *(if known)*
K162265

Device Name
CushionCast Moldable Cushion

Indications for Use *(Describe)*
The CushionCast Moldable Cushion is to be used by trained medical professionals for stable support and positioning of patients undergoing radiation therapy or other treatment in a clinic or hospital setting.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5.0 510(k) Summary

510(k) Owner

IZI Medical Products LLC
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Owings Mills, MD 21117
Phone: (410) 594-9403
Fax: (410) 594-0540
Contact Person: Qiang Cao, Quality Assurance and Regulatory Affairs Manager

Date Summary Prepared: August 10th, 2016

Device Name

Trade Name: CushionCast™ Moldable Cushion

Common or Usual Name: moldable cushion

Classification Name: Medical charged-particle radiation therapy system (21 CFR 892.5050)

Product Code: IYE

Predicate Devices

Klarity Mold Cushions (K132124)

Prior Submissions

There were no prior submissions for the subject device.

Device Description

The CushionCast™ is moldable stabilization cushions for radiation therapy patients. This product targets customers who require stabilization cushions for patients who are undergoing radiation therapy. The CushionCast™ is needed in order to mold to the shape of the patient's head to immobilize any movement during radiation therapy.

The cushion is constructed with a biocompatible and water resistant fabric and internal components, which include low viscosity casting resins that are sealed in pouches and polystyrene beads as filler material. To activate the cushion, the pouches are popped, and

the internal components are mixed for 2 minutes. The plug inserted in the vent tube is removed prior to the molding process. The vent tube serves to expel excess air to allow for an accurate mold. The mixture of the Part A and Part B liquid plastics should yield a hardened mold. The fully cured mold provides a dimensionally stable cushion required by radiotherapy systems.

Intended Use of the Device

The CushionCast™ Moldable Cushions are designed for the positioning and repositioning of patients receiving radiation therapy or other treatment. The moldable cushion is to be used by trained medical professionals for stable support and positioning of patients undergoing a radiation therapy or other treatment in a clinic or hospital setting.

Patient Population

The device is intended for use in patients undergoing external-beam radiation therapy or other teatment.

Environment of Use

The device is intended for use by a trained healthcare professional in a healthcare facility.

Claim of Substantial Equivalence

This product is substantially equivalent to existing patient positioning cushions currently being marketed as accessories to radiation therapy systems.

The equivalent device is Klarity Mold Cushion (AccuCushion) marketed by Klarity (K132124).

The Klarity Mold Cushions has an inner component of small polystyrene spheres. These are surrounded by a 1/16" layer of polycaprolactone thermoplastic that softens and is moldable at 150^0F. To use the Klarity Mold cushion, a therapist must first place the cushion in an oven or in a hot water bath to heat it to about 150^0F. At this temperature the cushion becomes moldable by hand and will remain moldable for about 5 to 8 minutes as it cools to room temperature.

The CushionCast™ is constructed with a biocompatible and water resistant fabric shell and internal components, which include small polystyrene beads and casting resins that are sealed in pouches. The mixture of Part A and Part B casting resins yields a durable mold with a hardening time approximately between 5 to 7 minutes after mixing. Fully cured molds provide a dimensionally stable cushion.

Like the Klarity Mold cushion, IZI CushionCast™ hardens to create a firm support cushion, conforming to and stabilizing the patient. The cushions also conform to the structure underneath the cushion, providing a means to specifically locate a patient on a treatment table or other support device.

Based on the similarity of design and construction of the CushionCast™ and the Klarity Mold Cushions, it is reasonable to expect that these devices will have similar properties and should function in a substantially equivalent fashion. Both devices are intended for use in positioning and re-positioning patients during radiation therapy procedures and are employed in clinically similar fashions.

A design verification study was conducted to ensure that the dimensional stability of the CushionCast™ meets necessary requirements. The study also indicated that the CushionCast™ performs equivalently to the Klarity Mold Cushions. It is reasonable to conclude that the CushionCast™ and Klarity Mold Cushion are substantially equivalent with respect to use, safety, and effectiveness.