Device 1: Klarity Vacuum Cushions

Date Prepared: July 1, 2013

Submitter: Klarity Medical Products, LLC
80 Westgate Drive
Newark, Ohio 43055
Tel: 740.788.8107

NOV 0 1 2013

Est. Registration # 1530561

Contact Person: Peter M Larson
President
Klarity Medical Products, LLC
Email: peter@klaritymedical.com

Trade Name: **Klarity Vacuum Cushions**

Common Name: Vacuum Cushion Immobilization System

Manufacturing Site: Klarity Medical Products, LLC
80 Westgate Drive
Newark, Ohio 43055
Tel: 740.788.8107

Classification Name: Medical charged-particle radiation therapy system,

Classification: Class 2 devices, 892.5050, IYE

Predicate Device: The SecureVac Immobilization System manufactured and marketed by Bionix Development Corporation of Toledo, Ohio. This device was classified as Class II by FDA and was given marketing clearance and assigned document control number K040773.

Intended Use: The Klarity vacuum cushions are designed for the positioning and repositioning of patients receiving external-beam radiation therapy.

Claim of Substantial Equivalence:

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

One equivalent device is the SecureVac Immobilization System manufactured and marketed by Bionix Development Corporation of Toledo Ohio. This device was classified as Class II by FDA

and was given marketing clearance and assigned document control number K040773.

The Bionix SecureVac Immobilization System consists of vacuum bags constructed with polyurethane coated nylon material and filled with small polystyrene spheres. Each bag is sealed airtight and fitted with a self-closing valve for ease of use. When air is evacuated, the SecureVac cushion contracts to hold a rigid shape over the course of the radiation therapy treatment.

The Klarity Vacuum Cushions are similarly constructed with a polyurethane coated nylon material. The vacuum bags are filled with small polystyrene spheres. The Klarity Vacuum cushions are airtight and fitted with a self-closing valve for ease of use. When air is evacuated, the cushions contract to hold a rigid shape over the course of the radiation therapy treatment.

The Klarity Vacuum Cushions function similarly to the Bionix SecureVac Systems. In clinical practice both devices are used in the same manner. The cushion is placed on a treatment table or baseboard, and the patient is then positioned on top of the vacuum cushion. A vacuum pump is connected to the check valve on the cushion and the air is evacuated. As the air is removed, the cushion compresses around the polystyrene spheres forming a rigid structure that conforms to the anatomy of the patient. When the air is completely evacuated the vacuum pump is disconnected. The cushion now forms a rigid indentation conforming to the anatomy of the patient. For each therapy session the patient can easily duplicate his/her previous position by slipping into the pre-formed depression made in the cushion, which enhances the accuracy of the radiation treatment.

Based on the similarity of design and construction of the Klarity Vacuum Cushions and the Bionix SecureVac Immobilization System, it is reasonable to expect that these devices will have similar properties and attenuation factors, and should function in substantially equivalent fashion during the radiation therapy process. Both devices are intended for use in positioning and re-positioning patients during radiation therapy procedures and are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the Klarity Vacuum Cushions and the Bionix SecureVac Immobilization System are substantially equivalent with respect to use, safety and effectiveness.

Device 2: Klarity Mold Cushions

Date Prepared: July 1, 2013

Submitter: Klarity Medical Products, LLC
80 Westgate Drive
Newark, Ohio 43055
Tel: 740.788.8107

Est. Registration # 1530561

Contact Person: Peter M Larson
President
Klarity Medical Products, LLC
Email: peter@klaritymedical.com

Trade Name: **Klarity Mold Cushion**

Common Name: Moldable Head and Neck cushions

Manufacturing Site: Klarity Medical Products, LLC
80 Westgate Drive
Newark, Ohio 43055
Tel: 740.788.8107

Classification Name: Medical charged-particle radiation therapy system,

Classification: Class 2 devices, 892.5050, IYE

Predicate Device: The MoldCare head and neck cushion marketed by Civco of Orange City, Iowa. This device was classified as Class II by FDA and was given marketing clearance and assigned document control number K982624.

Intended Use: The Klarity Mold Cushions are designed for the positioning and repositioning of patients receiving external-beam radiation therapy.

Claim of Substantial Equivalence:
This product is substantially equivalent to existing patient positioning cushions currently being marketed as accessories to radiation therapy systems.

One equivalent device is MoldCare head and neck cushion marketed by Civco (formerly Med-Tec) of Orange City, Iowa. This device was classified as Class II by FDA and was given marketing clearance and assigned document control number K982624. The

device is currently marketed by Civco as the AccuForm™ head and neck cushion.

The Civco MoldCare cushion has an inner body of polystyrene spheres mixed with a water activated resin. This mixture is surrounded by a soft nylon fabric cover. Before use, and when sold, the cushions are packaged in an air-tight aluminum foil case, to prevent moisture from reaching the cushions.

To use the cushion, a therapist will remove the packaging and apply water to the fabric of the cushion. The cushion is then placed and shaped under the patient's head or other body part. The inner resin reacts with the water and hardens in about 10 minutes, creating a solid formed support, stabilizing the patient.

The Klarity Mold Cushions are similarly constructed but with a different method of becoming secure. The cushion 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° F. The technology of this thermoplastic is commonly used in other radiation therapy devices, including our Klarity thermoplastic masks (510(k)#022708). The thermoplastic layer has a nylon stockinette material surrounding it, for patient comfort.

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° F. 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 warm cushion is extremely comfortable.

Like the MoldCare cushion, the Klarity Mold cushion 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 Klarity Mold Cushions and the Civco Moldcare cushion, 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. Therefore, it is reasonable to conclude that the Klarity Mold Cushion and the Civco Moldcare cushion, are substantially equivalent with respect to use, safety and effectiveness.

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

Klarity Medical Products LLC
% Mr. Peter Larson
President
80 Westgate Drive
NEWARK OH 43055

November 1, 2013

Re: K132124
Trade/Device Name: Klarity Vacuum Cushions and Klarity Mold Cushions
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 27, 2013
Received: October 4, 2013

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. 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.

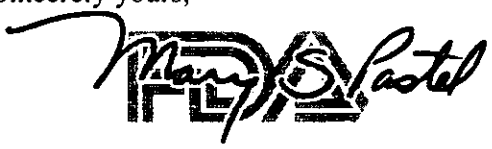
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132124

Device Names:

1. Klarity Vacuum Cushions
2. Klarity Mold Cushions

Indications for Use:

To be used by trained medical professionals for the stable support and positioning of patients undergoing external beam radiation therapy treatment in a clinic or hospital setting.

In particular, these items provide the stable positioning of patients in various positions, chosen to facilitate the most accurate treatment of tumors.

Patients are those that have been diagnosed and are undergoing treatment for cancerous tumors. Treatment is supervised and administered by licensed doctors and therapists trained in the application of radiation therapy treatments.

Prescription Use __x_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K132124