Aktina Medical Corporation
% Mr. Tony Spaccarotella
Director, Quality Assurance / Regulatory Affairs
360 North Route 9W
CONGERS NY 10920

September 25, 2019

Re: K192102
Trade/Device Name: Thermoplastic Mask
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: July 30, 2019
Received: August 5, 2019

Dear Mr. Spaccarotella:

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

Section 4

Indications for Use

No. of Pages Including Cover: 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*

K192102

Device Name
Thermoplastic Mask

Indications for Use *(Describe)*

Aktina Thermoplastic Masks are medical devices used for patient positioning and immobilization during external beam radiation therapy procedures. Thermoplastic masks are intended for single patient use for the duration o f the treatment.

Type of Use *(Select one or both, as applicable)*

IZ Prescription Use (Part 21 CFR 801 Subpart D) D Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of infonnation unless it displays a currently valid 0MB number."

Section 5

510(k) Summary

360 North Route 9W Congers, NY 10920 USA www.aktina.com 888.433.3380 Tel: 845.268.0101 Fax: 845.268.1700

510(k) Summary

K192102

In Compliance with 21 CFR Section 807.92(c)

1. General Provisions

Device Trade Name:	Thermoplastic Mask
Common Name:	Moldable Thermoplastic
Owner Name and Address:	Aktina Medical Corporation 360 North Route 9 W Congers, New York, 10920 Phone: 845-268-0101 Fax: 845-268-1700 Registration Number: 2436865

2. Contact Person:

Tony Spaccarotella, Director, QA/RA

3. Date Prepared:

July 1, 2019

4. Classification

This device is classified as a class II device according to 21 CFR 892.5050, "Medical charged-particle radiation therapy system." The product code is IYE.

5. Predicate Device

Embrace Thermoplastic, 510(k) No. K120335, manufactured by Bionix Development Corporation, 5154 Enterprise Blvd, Toledo, OH 43612 USA.

6. Description

This is a Traditional 510(k) for the Aktina Medical Thermoplastic Mask. The low-temperature thermoplastic mask is made of Aquaplast polycaprolactone sheets. When immersed in water heated to 70-75°C [160 to 170°F], the material softens, allowing the user to shape or stretch the mask over the contours of the patient's anatomy while cooling. When the material reaches room temperature, the mask hardens into the anatomical shape. The mask can then be placed over the patient treatment area to consistently immobilize the area from treatment to treatment. Predicate device manufacturers have used polycaprolactone materials for this intended use for over 25 years. The mask also has a polycarbonate frame with holes for mounting to the user's existing patient support hardware.

7. Intended Use

Aktina Thermoplastic Masks are medical devices used for patient positioning and immobilization during external beam radiation therapy procedures. Thermoplastic masks are intended for single patient use for the duration of the treatment.

8. Technological Characteristics

The Table below compares the technological characteristics of the Aktina Thermoplastic Mask to the Predicate Device:

Item	**Predicate Device, K120035** **Embrace Thermoplastic** **Bionix Development Corporation,** **5154 Enterprise Blvd, Toledo, OH 43612** **USA**	**This 510(k) Submission** **Thermoplastic Mask** **Aktina Medical Corp.,** **360 N. Route 9W, Congers, NY 10920** **USA**	**Equivalent or Better for Intended Use?**
1.	**Intended Use:** Immobilize patients receiving external beam radiation therapy.	**Intended Use:** Same as predicate.	Equivalent
2.	**Design:** Moldable plastic sheet used for patient immobilization. Heat is applied to the sheet to soften it and mold it to the shape of the patient anatomy. The mask is used for multiple treatments on a single patient. The sheet is pre-mounted to a non-patient contacting frame to interface with the user's existing support hardware.	**Design:** Same as predicate.	Equivalent
3.	**Components:** Low temperature thermoplastic sheet with non-low temperature plastic mounting frame.	**Components:** Same as predicate.	Equivalent
4.	**Technology:** 1. Perforated plastic sheets that soften for molding when exposed to heat. 2. Fastened to patient support equipment.	**Technology:** 1. Same as predicate. 2. Same as predicate.	Equivalent

5.	**Materials:** a. **Plastic sheet:** Polycaprolactone b. **Frame:** "Non-low temperature thermoplastic"	**Materials:** a. **Plastic sheet:** Same as predicate. b. **Frame:** Polycarbonate	a. Equivalent b. Equivalent
6.	**Biocompatibility:** Plastic sheet is biocompatible for skin contact up to 24 hours.	**Biocompatibility:** Same as predicate.	Equivalent
7.	**Sterility:** Non-sterile.	**Sterility:** Same as predicate.	Equivalent
8.	**Melting Temperature:** 160°F	**Melting Temperature:** Same as predicate.	Equivalent
9.	**Rigidity:** **Pressure (psi)** **Deflection (inches)** @ 5.08 psi 0.011 @ 10.4 psi 0.052	**Rigidity:** **Pressure (psi)** **Deflection (inches)** @ 5.08 psi 0.011 @ 10.4 psi 0.019	Equivalent at 5.08 psi Submitted device has less deflection at 10.4 psi
10.	**Shrinkage:** 0.3%	**Shrinkage:** 0.3%	Equivalent
11.	**Sheet Thickness:** 2.4mm	**Sheet Thickness:** Same as predicate.	Equivalent
12.	**Sheet Type:** Perforated sheets.	**Sheet Type:** Same as predicate.	Equivalent
13.	**Radiation Attenuation (X-ray):** Less than 2%	**Radiation Attenuation (X-ray):** Same as predicate device.	Equivalent

9. Performance Standards, Non-Clinical Testing, and Data

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this product

Specification testing has been performed for this device to show that the verification, validation and safety requirements have been met regarding:

- All specified functional, performance, safety and labeling requirements, such as biocompatibility, melting temperature, shrinkage, rigidity, and radiation attenuation.

- Assessment against ISO 14971 Risk Management requirements,
- Assessment against applicable sections of IEC Standard: 62366-1, Application of usability engineering to medical devices.

This device does not contain software.

The testing has demonstrated substantial equivalence or better when compared to the predicate device.

10. Clinical Testing

No clinical testing was performed in support of this pre-market submission.

11. Biocompatibility

The patient contact component for this device is the low-temperature thermoplastic mask material, which contacts the skin surface for less than 24 hours. This material has been shown to be biocompatible for the intended use when tested against the requirements of ISO 10993-1, -5 and -10 for cytotoxicity, irritation, and sensitization.

12. Conclusion Regarding of Substantial Equivalence

This device is similar in design, intended use, technological, physical and performance characteristics to the predicate device. No new issues of safety or effectiveness are introduced by using this device. Therefore, Aktina Medical Corp. believes that the Thermoplastic Mask is substantially equivalent to the predicate device.

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