September 3, 2025

Blessing Cathay Corporation
Jerry Su
Regulation Affairs Specialist
2F, No. 310, Jianguo 1st Road, Xinzhuang District
New Taipei City, 242047
Taiwan

Re: K252174
Trade/Device Name: AquaCast Mask
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: July 11, 2025
Received: July 11, 2025

Dear Jerry Su:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252174

Please provide the device trade name(s).

AquaCast Mask

Please provide your Indications for Use below.

AquaCast Mask is a device used for the positioning and immobilization of patient's head undergoing or receiving a course of external beam radiation therapy for the treatment of cancer. Thermoplastic Mask is intended as a single-patient reusable device only and are not sterile.

Please select the types of uses (select one or both, as applicable).

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

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K252174

510(k) Summary

1. Device Submitter

Blessing Cathay Corporation

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Contact Person:

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Regulation Affairs Specialist

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2. Device Name

Device Trade Name: AquaCast Mask

Common Name: Thermoplastic (moldable)

Classification Name: Accelerator, Linear, Medical

Regulation Description: Medical charged-particle radiation therapy system

Regulation Number: 21 CFR 892.5050

Device Class : Class II

Product Code : IYE

Panel: Radiology

3. Substantially Equivalent (predicate) device(s)

Device Trade Name: Embrace Thermoplastic

510(k) Number: K120335

Manufacturer: Bionix Development Corporation

4. Device Description

AquaCast Mask is used for the positioning and immobilization of patient's head undergoing or receiving a course of external beam radiation therapy for the treatment of cancer. The low temperature thermoplastic

mask is made of AquaCast polycaprolactone sheet for patient immobilization. Heat at a temperature of 150°F ~ 158°F is applied to the sheet to soften it and mold it to the shape of the patient anatomy. The perforated thermoplastic is pre-mounted to a non-patient contacting frame to interface with the user's existing support hardware and hold the patient's head in a fixed position for radiation therapy treatments

5. Indication for Use

AquaCast Mask is a device used for the positioning and immobilization of patient's head undergoing or receiving a course of external beam radiation therapy for the treatment of cancer. Thermoplastic Mask is intended as a single-patient reusable device only and are not sterile.

6. Technical characteristics

The table below compares technical characteristics of the AquaCast Mask to the Predicate device

Attribute	Predicate device	Subject device	Comparison and Explanation of Differences
Trade Name	Embrace Thermoplastic	AquaCast Mask	
510k number	K120335	NA	
Intended Use	Support and immobilize patients receiving external beam radiation therapy	Same as predicate	Equivalent
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	Same as predicate	Equivalent

	the user's existing support hardware.		
Technology	l. Perforated plastic sheets that soften for molding when exposed to heat. 2. Fastened to patient support hardware	Same as predicate	Equivalent
Composition	Polycaprolactone	Same as predicate	Equivalent
Sheet Thickness	2.4 mm and 3.2 mm	2.4 mm &3.2 mm	Equivalent
Features	Available as perforated and non-perforated sheets	Same as predicate	Equivalent
Soften temperature	160-170° F	150° ~ 160° F (65°C~71°C)	The difference does not raise any new risks.
Biocompatibility	Limited contact duration (<24 hours) for surface devices (skin).	Same as predicate	Equivalent
Sterility	Non-sterile.	Same as predicate	Equivalent
Rigidity	1.080 lbs/in^2	Same as predicate	Equivalent
Shrinkage	1.1%	Same as predicate	Equivalent
Radiation Attenuation (X-ray)	Less than 2%	Less than 2%	Equivalent

7. Performance data from non-clinical Testing

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

The following non-clinical testing was performed:

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Item	Test method	Test result
1.Rigidity of material	ASTM D790 Procedure A	1.080 lbs/in^2
2.Stretchiness of material	The piece are hung and placed in a heating pan at 71°C(160°F) during 31/2~4 minutes, and extension length(Stretched Length in Mm, SLM) is measured after taking out the water.	SLM=100
3.Shrinkage of material	Test piece is marked with a line to indicate an initial length. When removed from the water bath, the piece is stretched to 70% of the original length and cooled at the fixed stretched position at room temperature (21°C). The distance between two marks is measured in a free position after 24 hours. The shrinkage of the samples at room temperature is calculated in percentage (%)	0.9%
4.Softening(melting) time/temperature	Turn on heating pan, checking for sufficient water to cover AquaCast Mask. When it has become transparent, record the time period and temperature	49 ~53 seconds /71°C(160°F)
5.Solidification time/temperature	After AquaCast Mask has become transparent, remove it from heating pan. When it has become hardened, record the time period and temperature	31/2minutes/25°C(77°F)
6.Holding frame temperature	Prior to placing the softened AquaCast Mask over the patient, test to make sure it is not too warm, and record the temperature	21°C(69.8 °F)
7.Compatibility with the base plate testing,	Begin by hooking the edge of the thermoplastic sheet under the patient's chin, with the sheet tilted at a 45° angle to the plane of the face. Stretch the sheet superiorly six to eight inches, and then back down onto the indexing pins on the base plate (Klarity SRS Baseplate,K220539). Rotate the swivel clamps and tighten the screws, fastening the mask in place. Check if the locating pins (9) on the baseplate is fastened tightly.	Pass
8.Thermoplastic-skin contact temperature testing,	Using the transfer sheet remove the sheet from the water and blot off water with a dry towel. Make sure the mask is dry and cool. Record temperature when patient feels comfortable.	21°C(69.8 °F)

9.Validation of the cleaning	Clean the thermoplastic mask by using soap and water for 10 mins. Check the result.	Pass
10.Validation of the disinfection	Isopropyl or an ethanol-based disinfectant is used for the disinfection of thermoplastic mask when applied with a soft cloth. Check the result.	Pass
11.Shrinkage	AquaCast Mask was placed into a heating pan at a temperature of 71°C(160°F)for 3 1/2~4 minutes. AquaCast mask was removed and placed on a phantom head and left to dry. Once dry the mask was measured with a caliper. The mask was again measured after twenty-four hours. The difference in the size would determine the percentage of shrinkage.	1.5%
12.Radiation Attenuation (X-ray)	Measurements were taken on a Varian Clinic iX linear accelerator, for both 6 and 10 MV photons. Setup was performed 100 cm SAD, using an ion chamber at 10 cm depth of solid water, and 10 cm of solid water underneath. A 10 x10 cm field size was used, and 100 monitor units (MUs) were delivered. Readings were taken using an electrometer. Thermoplastic were in the form of thin uniform sheets, the same previously stated setup was followed, except that a sample of the thermoplastic sheet was placed on top of the solid water so that the field was entirely contained. Like before, 100 MUs were delivered. A attenuation correction factor, AF, was calculated for each thermoplastic sheet.	6 MV: 0.60% 10 MV: 0.47%

The patient contact component for the 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, -10 and -23 for cytotoxicity, irritation, and sensitization.

All non-clinical performance testing was completed to ensure that the devices fulfilled that the verification, validation and safety requirements and confirmed that the devices are as safe and effective as the predicate devices.

8. Performance data from clinical Testing

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

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9. Conclusion

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. The substantial equivalence comparison in this premarket submission together with the additional provided information has demonstrated substantial equivalence to the predicate device with respect to use, safety and effectiveness for their intended and indicated use.