MacroMedics BV
℅ Elizabeth Hajos
QARA Manager
Oostbaan 670
Moordrecht, South Holland 2841 ML
The Netherlands

Re: K213439
Trade/Device Name: FlexBoard™, EagleBoard™, BreastBoard SX™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: May 23, 2022
Received: May 27, 2022

Dear Elizabeth Hajos:

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 and Part 809); 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

Julie Sullivan, Ph.D.
Assistant Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213439

Device Name
FlexBoard™
EagleBoard™
BreastBoard SX™

Indications for Use *(Describe)*
The FlexBoard™ is indicated to aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) imaging systems.

The EagleBoard™ is indicated to aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) and Magnetic Resonance (MR) imaging systems.

The BreastBoard SX™ is indicated to aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) imaging 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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Product Name – Patient Positioning Devices
510(k) Summary; K213439

1. Submitter Details

Name: MacroMedics BV

Address: Oostbaan 670, 2841ML Moordrecht, The Netherlands

Contact Person: Elizabeth Hajos

Phone Number: +31 (0)182 389777

Prepared: 23-JUN-2022

2. Device Details

Trade Name: FlexBoard™, EagleBoard™, BreastBoard SX™

Common Name: Patient Positioning Devices

Classification: Class II

Regulation: EagleBoard™: 21 CFR 892.5050, 21 CFR 892.1000
FlexBoard™, BreastBoard SX™: 21 CFR 892.5050

Regulation Name: Medical Charged-Particle Radiation Therapy System,
System, Nuclear Magnetic Resonance Imaging

Product Code: EagleBoard™: IYE, LNH
FlexBoard™, BreastBoard SX™: IYE

Review Panel: Radiology

3. Predicate Device Details

510k Number	Device Name	Manufacturer	New Device for which Substantial Equivalence is claimed

K211001	C-Qual M™ Breastboard; Monarch™ Overhead Arm Positioner	MEDTEC, Inc. d/b/a "CIVCO Medical Solutions" and "CIVCO Radiotherapy"	FlexBoard™ EagleBoard™
K142420	BreastBoard LX™	MacroMedics BV	BreastBoard SX™

4. Subject Device Description, Intended Use, Technological Characteristics, Substantial Equivalence & Conclusion

4.1 Device (1) - FlexBoard™

Item code	Brand Name	Device Identifier
172110	FlexBoard™ base	08720168160492
172120	FlexBoard™ BTM-EX	08720168160508
173660	FlexBoard™ BTM-LX	08720168160966
174630	FlexBoard™ BTM-SX	08720168160744
122300	Upper AS TS/MBLX, set/2	08719425704005
122330	Cranial AS for BBLX/TS, set/2	08719425704029
125300	Rigid UAS set/2	08719425704319
125320	Adjust. UAS set/2	08719425704326

Intended Use: Positioning of the patient during radiotherapy and radio diagnostics, including MR where indicated.

Indications for Use: The FlexBoard™ is indicated to aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) imaging systems.

Description

The FlexBoard™ base is a lightweight baseplate with a locking system specially designed to host multiple types of breast treatment modules, in order to facilitate the positioning of the patient for breast and chest treatments. Multiple variants of FlexBoard™ breast treatment modules are available. To enable enhanced treatment possibilities, the 122930 EagleBoard™-2 Base device can be used with the 172120 FlexBoard™ BTM-EX breast module as part of the FlexBoard™ set-up.

Discussion of Indications for Use

The Indications for Use of the FlexBoard™ device and the predicate device differ in that the FlexBoard™ device is indicated for use with patients aged 18 and above, whilst the predicate device is indicated for use with patients aged 12 and above. This does not affect the safety or effectiveness of the device as breast and chest tumors do not typically occur in patients younger than 18 years and therefore the device is indicated for the typically appropriate population. The indications also differ in that, whilst the FlexBoard™ device is only indicated for use in Computed Tomography (CT)

imaging systems, the predicate device is indicated for use in both Computed Tomography (CT) and Magnetic Resonance (MR) imaging systems. This difference only indicates that there are fewer possibilities for the use of the FlexBoard™ device in imaging systems than there are with the predicate device, but this does not affect the safety or effectiveness of the device when the device is used as labelled.

Comparison of technological characteristics

The designs of the MacroMedics subject device and the predicate device are equivalent in shape, use and functionality. Both the MEDTEC, Inc. d/b/a "CIVCO Medical Solutions" and "CIVCO Radiotherapy" device and the MacroMedics devices feature a lightweight base plate which facilitates the placement of a breast treatment module and other devices and accessories. Both the predicate device and the FlexBoard™ device aid in the overhead-arm-positioning of the patient for breast and chest treatment. The technological characteristics differ in that the predicate device is indicated for use in the MRI environment whilst the FlexBoard™ device is not due to differences in materials. This difference has been addressed in the previous section.

Performance Data

Mechanical non-clinical testing and other performance data demonstrated that the devices performed as intended and that the differences in technological characteristics did not raise any new issues of safety or effectiveness.

Substantial equivalence summary

MacroMedics claims the proposed FlexBoard™ devices to be substantially equivalent to the devices previously cleared by the FDA in the 510(k) specified above. These devices are also cleared for use in a radiotherapy environment.

MacroMedics claims this equivalence because the proposed devices have equivalent designs and intended uses.

Conclusion

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

4.2 Device (2) – EagleBoard™

Model/Variants

Selling code	Brand name	Device Identifier
122850	EagleBoard™ MR	08719425704159
122860	T-Grip for EagleBoard™ MR	08719425702193
122870	U-Grip for EagleBoard™ MR	08719425702209
122930	EagleBoard™-2 Base	08720168160515
122940	EagleBoard™-2 M-Grip	08720168160522

122950	EagleBoard™-2 Base, MR	08720168161406
122960	EagleBoard™-2 Adaptor HS RE	08720168160539
122970	EagleBoard™-2 M-Grip, MR	08720168161413

Intended Use: Positioning of the patient during radiotherapy and radio diagnostics, including MR where indicated.

Indications for Use: The EagleBoard™ is indicated to aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) and Magnetic Resonance (MR) imaging systems.

Description

The EagleBoard™ devices consist of baseplates with a tapered design, and accessories, such as hand grips, which can be used together to support the positioning of the patient for breast and chest treatments. The 122930 EagleBoard™-2 Base device can be utilized both as part of a FlexBoard™ setup, or individually on the treatment table. The 122950 EagleBoard™-2 Base, MR and 122850 EagleBoard™ MR devices are intended to be utilized individually on the treatment table.

Discussion of Indications for Use

The Indications for Use of the EagleBoard™ device and the predicate device differ in that the EagleBoard™ device is indicated for use with patients aged 18 and above, whilst the predicate device is indicated for use with patients aged 12 and above. This does not affect the safety or effectiveness of the device as breast and chest tumors do not typically occur in patients younger than 18 years and therefore the device is indicated for the typically appropriate population.

Comparison of technological characteristics

The designs of the MacroMedics subject device and predicate device are equivalent in shape, construction, materials and functionality. Both the predicate device and the EagleBoard™ devices aid in the overhead-arm-positioning of the patient for breast and chest treatment. The EagleBoard™ devices differ from the predicate device in that the 122950 EagleBoard™-2 Base, MR and 122850 EagleBoard™ MR devices are designed to be used only individually on the treatment table.

Performance Data

Mechanical non-clinical testing and other performance data demonstrated that the devices performed as intended and that the differences in technological characteristics did not raise any new issues of safety or effectiveness.

Substantial equivalence summary

MacroMedics claims the proposed EagleBoard™ devices to be substantially equivalent to the devices previously cleared by the FDA in the 510(k) specified above. These devices are also cleared for use in a radiotherapy and/or the MR environment.

MacroMedics claims this equivalence because the proposed devices have equivalent designs and intended uses.

4.3 Device (3) – BreastBoard SX™

Selling code	Brand name	Device Identifier
172410	BreastBoard SX™	08719425707174
125300	Rigid UAS, set/2	08719425704319
125320	Adjust. UAS set/2	08719425704326
173510	Low Bridge Support, RE	08719425705446
173530	High Bridge Support, RE	08719425702759
121180	MaxSupport™ Extender	08719425703978
122590	BottomStop Adaption	08719425702155
172420	BreastBoard SX™ set/2 Profiles	08719425702254

Intended Use: Positioning of the patient during radiotherapy and radio diagnostics, including MR where indicated.

Indications for Use: The BreastBoard SX™ is indicated to aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) imaging systems.

Description

The BreastBoard SX™ is a lightweight baseplate designed to facilitate the positioning of patients for breast and chest treatments. The BreastBoard SX™ is adjustable and can be secured at various tilt positions. It features an adjustable bottom-stop, arm support possibilities for positioning the patient's arms above their head, place for a head rest, and fixation points for thermoplastic masks.

Discussion of Indications for Use

The Indications for Use of the BreastBoard SX™ device and the predicate device differ in that the Indications for the BreastBoard SX™ define an appropriate population of patients 18 and older undergoing radiation therapy of the breast and chest region, and specify image acquisition to support treatment planning, whilst the Indications of the predicate device are more general. This does not affect the safety and effectiveness of the device but only serves to outline the appropriate patient population and clinical uses more specifically.

Comparison of technological characteristics

The designs of the MacroMedics subject device and predicate device are equivalent in design, materials, construction and functionality. Both the predicate device and the BreastBoard SX™ device aid in the overhead-arm-positioning of the patient for breast and chest treatment. The technological characteristics differ in that the BreastBoard SX™ has fewer adjustment possibilities than the predicate device.

Performance Data

Mechanical non-clinical testing and other performance data demonstrated that the devices performed as intended and that the differences in technological characteristics did not raise any new issues of safety or effectiveness.

Substantial equivalence summary

MacroMedics claims the proposed BreastBoard SX™ devices to be substantially equivalent to the devices previously cleared by the FDA in the 510(k) specified above. These devices are also cleared for use in a radiotherapy environment.

MacroMedics claims this equivalence because the proposed devices have equivalent designs and intended uses.

Conclusion

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