MacroMedics BV
℅ Elizabeth Hajos
QA/RA Director
Oostbaan 670
Moordrecht, South Holland 2841 ML
NETHERLANDS

February 17, 2023

Re: K222977
Trade/Device Name: DSPS-Prominent™ Masks; DSPS-Prominent™ Baseplate, MR; CouchStrip
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE, LNH
Dated: September 26, 2022
Received: September 28, 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); 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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.02.17 10:29:17 -05'00'

Lora D. Weidner, Ph.D
Assistant Director
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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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)*
K222977

Device Name
DSPS-Prominent™ Masks, DSPS-Prominent™ Baseplate, MR, CouchStrip

Indications for Use *(Describe)*

DSPS-Prominent Masks, DSPS-Prominent Baseplate, MR:

Positioning and immobilization of the patient during radiotherapy. This includes positioning and immobilization of the patient during image acquisition to support treatment, such as in Magnetic Resonance (MR) and Computed Tomography (CT) Imaging Systems.

CouchStrip:

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

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.

K222977

Product Name – Patient Positioning Devices

510(k) Summary

Statement: Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "510(k) Summarises and 510(k) Statements" (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

1. Submitter Details

Name:	MacroMedics BV
Address:	Oostbaan 670, 2841ML Moordrecht, The Netherlands
Contact Person:	Elizabeth Hajos
Phone Number:	+31 (0)182 389777
Date Prepared:	16-FEB-2023

2. Device Details

Trade Name:	DSPS-*Prominent*™ Masks, DSPS-*Prominent*™ Baseplate, MR, CouchStrip
Common Name:	Patient Positioning Devices
Classification:	Class II
Regulation:	21 CFR 892.5050
Regulation Name:	Medical Charged-Particle Radiation Therapy System
Product Code:	IYE, LNH
Review Panel:	Radiology

3. Predicate Device Details

510k Number	Device Name	Manufacturer	New Device for which Substantial Equivalence is claimed
K142420	DSPS & SSPS thermoplastic masks	MacroMedics BV	DSPS-*Prominent*™ Masks
K142420	DSPS & SSPS cradles, ExaFix-IMRT baseplate MR	MacroMedics BV	DSPS-*Prominent*™ baseplate, MR
K212909	CouchStrips	MacroMedics BV	CouchStrip

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

4.1 Device (1) - DSPS-*Prominent*™ Masks

Item code	Brand Name	Device Identifier
113950	Mask DSPS®-PROSVRL, set/5	08720168162250
113960	Mask DSPS®-PROS, set/5	08720168162205
113970	Mask DSPS®-PROSVR, set/5	08720168162236
113980	Mask DSPS®-PROSL, set/5	08720168162267

Intended Use/ Indications for Use:

Positioning and immobilization of the patient during radiotherapy. This includes positioning and immobilization of the patient during image acquisition to support treatment, such as in Magnetic Resonance (MR) and Computed Tomography (CT) Imaging Systems.

Description:

The DSPS-*Prominent* Masks are facial and occipital thermoplastic masks which are used as part of the DSPS-*Prominent* system to facilitate accurate positioning and immobilization of the head, neck and shoulder region of the patient.

Differences in Indications for Use:

The differences between the Indication for Use statements of the predicate device and the new device do not affect the safety and effectiveness of the devices and are not critical to their

intended use because they only represent minor changes which serve to improve the completeness and clarity of the Indications for Use statement and do not alter the purpose or use of the devices.

Comparison of technological characteristics:

The designs of the MacroMedics subject device and the predicate device are equivalent in materials, construction, use and functionality. Both the MacroMedics DSPS & SSPS thermoplastic masks and the new MacroMedics DSPS-*Prominent* masks are thermoplastic masks made of the same thermoplastic materials which become pliable when heated and rigid when cooled, thus being able to be moulded to the contours of the patient to form a personalised mask. In both cases, occipital and facial masks are available. In both cases, the thermoplastic material is attached to a plastic frame (part of the mask), and this plastic frame is designed to be fixed to the frame of another device to facilitate patient positioning within a 'double shell' (facial and occipital) mask system. In both cases, the masks are MR Safe. In both cases, the positioning of the head and neck is supported, with the predicate device also offering facial 'head, neck and shoulder' masks. The DSPS-*Prominent* masks additionally allow the shoulder region of the patient to be positioned and immobilized within occipital masks.

Substantial equivalence summary:

MacroMedics claims the proposed DSPS-*Prominent™* 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 MR environment.

MacroMedics claims this equivalence because the proposed devices have equivalent designs and intended uses. These products have very similar positioning and immobilization characteristics.

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) – DSPS-*Prominent™* Baseplate, MR

Selling code	Brand name	Device Identifier
113820	DSPS-Prominent™ baseplate, MR	08720168162182
113710	MLDRM tool	08720168162250

Intended Use/ Indications for Use:

Positioning and immobilization of the patient during radiotherapy. This includes positioning and immobilization of the patient during image acquisition to support treatment, such as in Magnetic Resonance (MR) and Computed Tomography (CT) Imaging Systems.

Description:

The DSPS-*Prominent* baseplate, MR is an MR Safe baseplate which supports the positioning and immobilization of the patient within DSPS-*Prominent* occipital and facial masks. The device features a cantilevered frame on the cranial side which facilitates the use of both facial and occipital head, neck and shoulder masks. The device is fixed to the couch using couch strips.

Differences in Indications for Use:

The differences between the Indication for Use statements of the predicate device and the new device do not affect the safety and effectiveness of the devices and are not critical to their intended use because they only represent minor changes which serve to improve the completeness and clarity of the Indications for Use statement and do not alter the purpose or use of the devices.

Comparison of technological characteristics:

The designs of the MacroMedics subject device and predicate devices are equivalent in shape, construction, materials and functionality. The new device combines the features of the predicate devices in a glass fiber, MR Safe baseplate which facilitates the positioning of the patient within a 'double-shell' (facial and occipital mask) system. The predicate devices are also MR Safe, composed of glass fiber and facilitate the positioning of the patient within a 'double-shell' system. The predicate devices enable the patient to be positioned within 'head only' occipital masks and either 'head only' or 'head, neck and shoulder' facial masks, whilst the new device enables the patient to be positioned within both facial and occipital 'head, neck and shoulder' thermoplastic masks.

Substantial equivalence summary:

MacroMedics claims the proposed 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 MR environment.

MacroMedics claims this equivalence because the proposed devices have equivalent designs and intended uses. These products have very similar positioning and immobilization characteristics.

4.3 Device (3) – CouchStrip

Selling code	Brand name	Device Identifier
147410	CouchStripCS53FGF-PRO	08720168162199

Intended Use/ Indications for Use:

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

Description:

CouchStrips are bars which connect the patient positioning device onto the treatment table at indexed positions. The DSPS-*Prominent* CouchStrip is MR Safe.

Comparison of technological characteristics:

The designs of the MacroMedics subject device and predicate device are equivalent in shape, design, construction, materials and functionality. Both devices are MR Safe, glass fiber strips which feature three plastic 'positioning pins'. Both devices serve to enable a baseplate to be fixed to the treatment table.

Substantial equivalence summary:

MacroMedics claims the proposed device 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 MR environment.

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

Testing Performed:

Clinical and non-clinical testing was performed. Non-clinical performance testing was completed to ensure that the devices fulfilled the defined requirements. Clinical testing was performed to ensure that the use of the devices enables submillimetre positional accuracy to be achieved. The testing confirmed that the new devices are as safe and effective as the predicate devices.

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.