March 19, 2025

MacroMedics BV
Elizabeth Hajos
QARA Director
Oostbaan 670
Moordrecht
Netherlands

Re: K250429
Trade/Device Name: DSPS-Prominent® baseplate, MR (113820); DSPS-Prominent® baseplate (113120); DSPS-Prominent® Cradle-I (113140); DSPS-Prominent® Cradle-II (113150); DSPS-Prominent® Cradle-III (113160); DSPS-Prominent® Cradle-IV (113170); DSPS-Prominent® Cradle-VI (113180); DSPS-Prominent® Cradle-VII (113260); Mask DSPS®-PROSCVRL set/5 (113760); Mask DSPS®-PROSC set/5 (113770); Mask DSPS®-PROSCVR set/5 (113780); Mask DSPS®-PROSCL set/5 (113790); Mask DSPS®-PROSHVRL set/5 (113890); Mask DSPS®-PROSH set/5 (113910); Mask DSPS®-PROSHL set/5 (113920); Mask DSPS®-PROH, set/5 (113930); Mask DSPS®-PROSHVR set/5 (113940); Mask DSPS®-PROSVRL, set/5 (113950); Mask DSPS®-PROS, set/5 (113960); Mask DSPS®-PROSVR, set/5 (113970); Mask DSPS®-PROSL, set/5 (113980); Mask DSPS®-PRO, set/5 (113990); DSPS-Prominent® SH profile set/2 (113090); DSPS PRO Mask Shim Set HNS (113250); DSPS PRO Mask Shim Set HO (113270); DSPS®-PRO Coil Ref Tool (113710); Handgrips HNS, set/2 (111730)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE, LNH
Dated: February 12, 2025
Received: February 14, 2025

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 (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250429

Device Name

DSPS-Prominent® baseplate, MR (113820);
DSPS-Prominent® baseplate (113120);
DSPS-Prominent® Cradle-I (113140);
DSPS-Prominent® Cradle-II (113150);
DSPS-Prominent® Cradle-III (113160);
DSPS-Prominent® Cradle-IV (113170);
DSPS-Prominent® Cradle-VI (113180);
DSPS-Prominent® Cradle-VII (113260);
Mask DSPS®-PROSCVRL set/5 (113760);
Mask DSPS®-PROSC set/5 (113770);
Mask DSPS®-PROSCVR set/5 (113780);
Mask DSPS®-PROSCL set/5 (113790);
Mask DSPS®-PROSHVRL set/5 (113890);
Mask DSPS®-PROSH set/5 (113910);
Mask DSPS®-PROSHL set/5 (113920);
Mask DSPS®-PROH, set/5 (113930);
Mask DSPS®-PROSHVR set/5 (113940);
Mask DSPS®-PROSVRL, set/5 (113950);
Mask DSPS®-PROS, set/5 (113960);
Mask DSPS®-PROSVR, set/5 (113970);
Mask DSPS®-PROSL, set/5 (113980);
Mask DSPS®-PRO, set/5 (113990);
DSPS-Prominent® SH profile set/2 (113090);
DSPS PRO Mask Shim Set HNS (113250);
DSPS PRO Mask Shim Set HO (113270);
DSPS®-PRO Coil Ref Tool (113710);
Handgrips HNS, set/2 (111730)

Indications for Use *(Describe)*

All devices apart from Handgrips HNS, set/2 (111730):

Positioning and immobilization of the patient during radiotherapy. This includes positioning and immobilization of the patient during image acquisition to support treatment.

Handgrips HNS, set/2 (111730):

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.

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K250429

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: 13-MAR-2025

2. Device Details

Trade Name:
DSPS-*Prominent*® baseplate, MR (113820);
DSPS-*Prominent*® baseplate (113120);
DSPS-*Prominent*® Cradle-I (113140);
DSPS-*Prominent*® Cradle-II (113150);
DSPS-*Prominent*® Cradle-III (113160);
DSPS-*Prominent*® Cradle-IV (113170);
DSPS-*Prominent*® Cradle-VI (113180);
DSPS-*Prominent*® Cradle-VII (113260);
Mask DSPS®-PROSCVRL set/5 (113760);
Mask DSPS®-PROSC set/5 (113770);
Mask DSPS®-PROSCVR set/5 (113780);
Mask DSPS®-PROSCL set/5 (113790);
Mask DSPS®-PROSHVRL set/5 (113890);
Mask DSPS®-PROSH set/5 (113910);
Mask DSPS®-PROSHL set/5 (113920);
Mask DSPS®-PROH, set/5 (113930);
Mask DSPS®-PROSHVR set/5 (113940);
Mask DSPS®-PROSVRL, set/5 (113950);

Mask DSPS®-PROS, set/5 (113960);
Mask DSPS®-PROSVR, set/5 (113970);
Mask DSPS®-PROSL, set/5 (113980);
Mask DSPS®-PRO, set/5 (113990);
DSPS-*Prominent*® SH profile set/2 (113090);
DSPS PRO Mask Shim Set HNS (113250);
DSPS PRO Mask Shim Set HO (113270);
DSPS®-PRO Coil Ref Tool (113710);
Handgrips HNS, set/2 (111730)

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	Predicate Device Name	Manufacturer	Subject Device for which Substantial Equivalence is claimed
K222977	DSPS-*Prominent* Baseplate, MR	MacroMedics BV	DSPS-*Prominent* Baseplate, MR
K222977	DSPS-*Prominent* Baseplate, MR	MacroMedics BV	DSPS-*Prominent* Baseplate
K222977	DSPS-*Prominent* Baseplate, MR	MacroMedics BV	DSPS-*Prominent* Cradle
K222977	DSPS-*Prominent* Masks	MacroMedics BV	DSPS-*Prominent* Masks

4. Indications For Use of Subject Devices

All devices apart from Handgrips HNS, set/2 (111730):

Positioning and immobilization of the patient during radiotherapy. This includes positioning and immobilization of the patient during image acquisition to support treatment.

Handgrips HNS, set/2 (111730):

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

5. Subject Device Description, Technological Characteristics and Substantial Equivalence

5.1 Device (1) - DSPS-*Prominent* Baseplate, MR

Item code	Brand Name	Device Identifier
113820	DSPS-*Prominent*® baseplate, MR	08720168162182
113710	DSPS®-PRO Coil Ref Tool	08720168162694

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 and head only masks. The device is fixed to the couch using couch strips. A Coil Reference Tool accessory is available.

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 a minor change which does not affect the purpose or use of the devices.

Comparison of technological characteristics:

The technological characteristics of the device have not changed.

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 environment.

MacroMedics claims this equivalence because the proposed devices are the same: the design, use, technological characteristics and all other aspects are the same. The only difference is the minor difference in indications for use which does not affect either the safety and effectiveness or the substantial equivalence of the 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.

5.2 Device (2) – DSPS-Prominent Baseplate

Selling code	Brand name	Device Identifier
113120	DSPS-*Prominent*® baseplate	08720168160140
111730	Handgrips HNS, set/2	08720168162908

Description:

The DSPS-*Prominent* baseplate 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 and head only masks. The device is fixed to the couch using couch strips. Optional accessory hand grips are available.

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 a minor change which does not affect the purpose or use of the devices.

Comparison of technological characteristics:

The designs of the MacroMedics subject device and predicate device are equivalent in shape, materials, construction and functionality. Both devices are constructed of rigid materials and are baseplates which support the upper anatomy of the patient. Both devices feature a cantilevered frame at the cranial end which facilitates the use of DSPS-*Prominent* facial and occipital masks. Both devices are fixed to the couch using couch strips. The difference between the predicate device and the new device is that the new device is constructed of carbon fibre rather than glass fibre.

Substantial equivalence summary:

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.

MacroMedics claims this equivalence because the proposed devices are the same in every way apart from the material, which is equivalent: the devices have the same design, positioning features, and general technological characteristics. The minor difference in indications for use does not affect either the safety

and effectiveness or the substantial equivalence of the devices. The difference in material also does not raise any questions of safety and effectiveness when the device is used in accordance with its labelling.

5.3 Device (3) – DSPS-Prominent Cradle

Selling code	Brand name	Device Identifier
113140	DSPS-*Prominent®* Cradle-I	08720168162557
113150	DSPS-*Prominent®* Cradle-II	08720168162564
113160	DSPS-*Prominent®* Cradle-III	08720168162779
113170	DSPS-*Prominent®* Cradle-IV	08720168162786
113180	DSPS-*Prominent®* Cradle-VI	08720168162793
113260	DSPS-*Prominent®* Cradle-VII	08720168163325

Description:

The DSPS-*Prominent* cradles support the positioning and immobilization of the patient within DSPS-*Prominent* occipital and facial masks. The devices feature a cantilevered frame which facilitates the use of both facial and occipital head, neck and shoulder masks and head only masks. The device is required to be fixed to a baseplate.

Comparison of technological characteristics:

The designs of the MacroMedics subject device and predicate device are equivalent in shape, materials, construction and functionality. Both devices are constructed of rigid materials and feature a cantilevered frame which facilitates the use of DSPS-*Prominent* facial and occipital masks. Both devices are fixed to an underlying device. The difference between the predicate device and the new devices is that the predicate device was a glass fibre baseplate featuring a (glass fibre) cantilevered frame, whilst the new devices are carbon fibre cradles featuring the same cantilevered frame reproduced in carbon fibre; the new devices are shorter devices and are required to be attached to an underlying baseplate rather than to the treatment table directly (as is the case with the baseplate devices).

Substantial equivalence summary:

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.

MacroMedics claims this equivalence because the proposed devices are significantly similar. Specifically, they are governed by the same design principles and feature the same characteristics for patient positioning. Moreover, their technological characteristics and use are significantly similar. The differences, including the minor difference in indications for use, do not affect either the safety and effectiveness or the substantial equivalence of the devices.

5.4 Device (4) - DSPS-Prominent Masks

Selling code	Brand name	Device Identifier
113760	Mask DSPS®-PROSCVRL set/5	08720168162854
113770	Mask DSPS®-PROSC set/5	08720168162861
113780	Mask DSPS®-PROSCVR set/5	08720168162878
113790	Mask DSPS®-PROSCL set/5	08720168162885
113890	Mask DSPS®-PROSHVRL set/5	08720168162571
113910	Mask DSPS®-PROSH set/5	08720168162595
113920	Mask DSPS®-PROSHL set/5	08720168162618
113930	Mask DSPS®-PROH, set/5	08720168162748
113940	Mask DSPS®-PROSHVR set/5	08720168162649
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
113990	Mask DSPS®-PRO, set/5	08720168162755
113090	DSPS-*Prominent*® SH profile set/2	08720168163356
113250	DSPS PRO Mask Shim Set HNS	08720168163387
113270	DSPS PRO Mask Shim Set HO	08720168163394

Description:

The DSPS-*Prominent* Masks are facial and occipital thermoplastic masks which are used together with a DSPS-*Prominent* baseplate or cradle to facilitate accurate positioning and immobilization of the head and neck or head, neck and shoulder region of the patient. The Masks which do not support the positioning of the shoulders are termed 'head only' masks. Shoulder Profile and Shim accessories are available.

Comparison of technological characteristics:

The designs of the MacroMedics subject device and predicate device are equivalent in shape, materials, construction and functionality. The predicate and new devices are thermoplastic masks which are constructed of the same materials and are intended to be secured to the frame of another device (cradles/ baseplates). The thermoplastic materials become pliable when heated and rigid when cooled, thus being able to be molded to the contours of the patient to form a personalized mask. The technological characteristics have not changed. The only difference is that 'head only' mask models are now also included. The 'head only' masks are shorter masks which do not extend to the shoulder region.

Substantial equivalence summary:

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.

MacroMedics claims this equivalence because the proposed devices are significantly similar. Specifically, they are governed by the same design principles, they are composed of the same materials, their general

technological characteristics are the same, and their use is significantly similar. The minor differences, including the minor difference in indications for use, do not affect either the safety and effectiveness or the substantial equivalence of the devices.

6. General

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 supports the achievement of submillimeter positional accuracy. In addition, attenuation measurements were taken, and water equivalence measurements were calculated, for the devices. 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.