May 11, 2022

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

Re: K212909
Trade/Device Name: Vacuum Cushions, FeetSupports, LEPS (Lower Extremities Positioning System) CouchStrips
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, LNH
Dated: April 7, 2022
Received: April 18, 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,

Julie Sullivan, Ph.D.
Assistant Director
DHT 8C: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212909

Device Name
VacuumCushions, Feetsupports, LEPS (Lower Extremities Positioning System) CouchStrips

Indications for Use *(Describe)*
Both the Intended Use and the Indications for Use of the devices included in this submission are as follows:

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Product Name – Patient Positioning Devices

510(k) Summary K212909

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: Jaap Drenth

Phone Number: +31 (0)182 389777

Date Prepared: 09-SEP-2021

2. Device Details

Name: VacuumCushions, FeetSupports, LEPS (Lower Extremities Positioning System), CouchStrips

Trade Name: MacroMedics

Common Name: Patient Positioning Devices

Classification: Class II

Regulation: 21 CFR 892.5050, 21 CFR 892.1000

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

Product Code: IYE, LNH

Review Panel: Radiology

3. Predicate Device Details

510k Number	Device Name	Manufacturer
K180021	Cushions (Vac-Lok)	MEDTEC, Inc. d/b/a "CIVCO Medical Solutions" and "CIVCO Radiotherapy"
K142420	LEPS (Lower Extremities Positioning System), FeetSupports	MacroMedics BV
K142420	CouchStrips	MacroMedics BV

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

4.1 Device (1) - VacuumCushions

Model/Variants

Selling code	Brand name	Device Identifier
155110	VacuumCushion 30x40	08719425702940
155140	VacuumCushion 25x50	08719425702957
155150	VacuumCushion 50x70 T	08719425702964
155210	VacuumCushion 50x70	08719425702971
155300	VacuumCushion 65x65	08719425702988
155400	VacuumCushion 100x70	08719425702995
155410	VacuumCushion 100x80	08719425703008
155430	VacuumCushion 120x80	08719425703015
155450	VacuumCushion 100x150	08719425703022
155510	VacuumCushion 200x100	08719425703039
155520	VacuumCushion 120x120 T	08719425705194
123450	VacuumCushion, abdom.S	08719425702650
123470	VacuumCushion, abdom.XL	08719425702667

Intended Use and/or Indications for Use

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

Description

The VacuumCushions (Vacuum Cushions) are cushions which are formed around the patient to create a rigid impression of the patient's anatomy in order to facilitate reproducible positioning.

The impression is created through drawing the air out of the cushion whilst the patient is in the desired position.

Comparison of technological characteristics

The designs of the MacroMedics and predicate device are equivalent in shape, construction, materials and functionality. Both the MEDTEC, Inc. d/b/a "CIVCO Medical Solutions" and "CIVCO Radiotherapy" devices and the MacroMedics devices are made out of Polystyrene Beads in Polyurethane-coated Nylon bag, and feature a valve for creating the vacuum.

Substantial equivalence summary

MacroMedics claims the proposed VacuumCushions 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 MR environment.

MacroMedics claims this equivalence because the proposed devices have equivalent designs, intended uses, target populations and used materials. These products have very similar positioning and immobilization characteristics for use in radiotherapy and radio-diagnostics.

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) – FeetSupports

Model/Variants

Selling code	Brand name	Device Identifier
130260	FeetSupport™, rotatable, 3P	08719425702308
130250	FeetSupport™, fixed, indexable on LEPS and DSCP platforms, 3P	08719425702315
130460	FeetSupport 2.0™, rotatable	08720168160263
130450	FeetSupport 2.0™, fixed	08720168160362

Intended Use and/or Indications for Use

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

Description

The FeetSupports facilitate the positioning of the patient's feet. They are available in fixed and rotatable variants and can be fixed to various baseplates and couchtops.

Comparison of technological characteristics

The designs of the MacroMedics subjective device (the Feetsupports which are part of the LEPS), and predicate device are equivalent in shape, construction materials and functionality.

Substantial equivalence summary

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

MacroMedics claims this equivalence because the proposed devices have equivalent designs, intended uses, target population and used materials. These products have similar position and immobilization characteristics for use radiotherapy and radio-diagnostics.

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.

4.3 Device (3) - LEPS (Lower Extremities Positioning System)

Model/Variants

LEPS with the rotatable FeetSupport
LEPS with the fixed FeetSupport

Selling code	Brand name	Device Identifier
130300	LEPS™, FeetSupport™, rot.	08719425702261
130310	LEPS™ FeetSupport™, fixed	08719425702278
130260	FeetSupport™, rotatable	08719425702308
130250	FeetSupport™, fixed	08719425702315
130200	LEPS™ baseplate	08719425702322
130420	LEPS™ baseplate short	08719425709772
130100	KneeSupport™	08719425702285
130120	KneeSupport™ LiftBlock™	08719425702292
130130	KneeSupport™ low,plastic	08719425707129
130140	KneeSupport™, plastic	08719425707136
130350	Shoulder retr. for LEPS™	08719425702339

Intended Use and/or Indications for Use

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

Description

The LEPS enables a patient's lower extremities to be positioned, using a Kneesupport, FeetSupport and, as desired, a LiftBlock. Shoulder Retractors can also be used to support the retraction of the patient's shoulders. The base of the LEPS is the LEPS baseplate.

The LEPS Short baseplate enables the patient's feet to be positioned using a FeetSupport.
The LEPS baseplates can be positioned on the couch treatment table using couch strips.

Comparison of technological characteristics

The designs of the MacroMedics subjective device and predicate device are equivalent in shape, construction materials and functionality. The MacroMedics predicate device and the subject device are made out of the same materials.

Substantial equivalence summary

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

MacroMedics claims this equivalence because the proposed devices have equivalent designs, intended uses, target population and used materials. These products have similar position and immobilization characteristics for use radiotherapy and radio-diagnostics.

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.

4.4 Device (4) - CouchStrips

Model/Variants

Selling code	Brand name	Device Identifier
147930	CouchStrip CS53FGF-EX	08719425709802
147110	CouchStrip CS53FCF-IB	08720168160317
147130	CouchStrip CS53FCF-S	08720168160188
147140	CouchStrip CS50FCF-S	08720168160324
147950	CouchStrip CS50FCF-EX	08719425705606
147960	CouchStrip CS53FCF-EX	08719425709796
155950	VacuumCushion Pos.Strip MR	08720168160355
147150	CouchStrip CS53FGF-S	08720168160331

155870	VacuumCushion positioning strip	08719425705231

Description

CouchStrips are bars which connect the patient positioning device onto the treatment table at indexed positions. Depending on the indexing system of the treatment table, its width, the preference in transverse adjustability and required MR safety, different types and indexing styles are available. VacuumCushion Positioning Strips (VCPS) are CouchStrips which are placed onto other CouchStrips in order to secure a VacuumCushion in place.

Indications for Use

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

Comparison of technological characteristics

The designs of the MacroMedics subjective device and predicate device are equivalent in shape, construction materials and functionality.

Substantial equivalence summary

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

MacroMedics claims this equivalence because the proposed devices have equivalent designs, intended uses, target population and used materials. These products have very similar position characteristics for use radiotherapy and radio-diagnostics.

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.