DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 27, 2015

MacroMedics BV
% Ms.Caroline de Keijzer
Quality Manager
Kouwe Hoek 18
2741 PX Waddinxveen
THE NETHERLANDS

Re: K142420
Trade/Device Name: Patient Positioning Devices
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: II
Product Code: IYE, LNH
Dated: February 20, 2015
Received: February 23, 2015

Dear Ms. de Keijzer:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

2.5-Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142420

Device Name

Patient Positioning Devices

Indications for Use *(Describe)*

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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510(k) Summary of safety and effectiveness (As required by 21 CFR 807.92)

Applicant:	**MacroMedics BV**
Address:	Kouwe Hoek 18, 2741PX, Waddinxveen, The Netherlands
Phone:	0031-(0)182 389777
Fax:	0031-(0)182 389778
Contact person:	Caroline de Keijzer, Quality and Regulatory Manager
Prepare date:	June 13, 2014
Establishment Registration Number:	10046168
FDA Type:	Traditional 510(k)
Common name:	-Head and neck positioning systems. -Lung and thorax positioning systems -Pelvic and lower extremities positioning systems -SBRT systems -Thermoplastic positioning systems
Trade / Proprietary name:	Patient Positioning Devices
Classification:	Class 2 devices, 892.5050, IYE, LNH
Review panels:	Radiology
Performance standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic act.

Head and neck positioning systems (1/2)

ExaFix-5
ExaFix-5A
ExaTilt
ExaFix-IMRT baseplate
ExaFix-IMRT baseplate MR
MaxSupport 1,2,3,4,5,6,7
Block low, Block high
Wedge 7, 5, 10, 15
MaxSupport 25,35,45

Intended use / Indications for use:

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

Device description:

Baseplates and headsupports which are designed to position the head and neck and on which thermoplastic masks can be attached to fix the head and neck of the patient. Baseplates can be positioned on the couch using CouchStrips. The ExaFix-IMRT baseplates are attached onto the couches and extent the head of the patient from the couch at the cranial side. Various accessories offered for specific patient head and neck set-ups. The different headsupports are designed for different head positions. Different blocks are available for lifting the head, wedges and ExaTilt to incline the head. For the Exafix-5 baseplate an acrylic alternative (Exafix-5a) is available for identical head- and neck positioning in the MR environment. For the IMRT baseplates a glassfiber alternative (Exafix IMRT baseplate MR) is available for identical head- and neck positioning in MR environment. The MR safe devices have a 3Pin slot on the bottomside and are compatible with the glassfiber 3Pin CouchStrip. The MR unsafe devices are not compatible with the 3Pin MR safe CouchStrip, which prevents the use in the wrong environment.

MacroMedics devices	Predicate devices:	510(k) number:
ExaFix-5	Sinmed Posifix-2	K060737 (IYE)
ExaFix-5A	Sinmed Posifix-1	K060737 (IYE) K093738 (LNH, reference device)
ExaTilt	Sinmed Positilt	K060737 (IYE)
ExaFix-IMRT baseplate	Sinmed IMRT baseplate	K060737 (IYE)
ExaFix-IMRT baseplate MR	Sinmed IMRT baseplate	K060737 (IYE) K093738 (LNH, reference device)
MaxSupport 1,2,3,4,5,6,7	Sinmed headsupports	K060737 (IYE) K093738 (LNH, reference device)
Block low, Block high Wedge 7, 5, 10, 15 MaxSupport 25,35,45	Sinmed Blocks and wedges	K060737 (IYE)

Head and neck positioning systems (2/2)

Comparision of technological characteristics:

The designs of the MacroMedics and predicate head and neck positioning systems are equivalent in shape, construction materials and functionality. Both the Sinmed devices and the MacroMedics devices are made out of carbon fiber, PE foam and acrylic. MacroMedics uses glass fiber for the MR safe alternative of the carbon fiber IMRT baseplates. The Sinmed headsupports are made out of PE foam, the MacroMedics headsupports have a PU-foam alternative. Both the biocompatibility and the MR safety of these new materials have been described in this 510(k).

Substantial equivalence summary:

MacroMedics claims the proposed head and neck positioning systems 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, patient positioning and used materials. Although small technological differences exist, these products have similar position and immobilization characteristics for use radiotherapy and radio-diagnostics.

Conclusions:

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. The biological safety evaluation and the MR safety evaluation have supported the claim of safety when used in an MR environment and in contact the patient's skin.

Lung and thorax positioning systems (1/2)

BreastBoard LX
ThoraxSupport
ThoraxSupport MR

Intended use / Indications for use:

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

Device description:

The BreastBoard LX and ThoraxSupports are devices which position the breast and lung area of a patient. The arms are placed above the head and a headsupport can be placed into the baseplate. The backsupport of the BreastBoard LX can be tilted, to tilt the upperpart of the patient´s body for other treatment possibilities. The ThoraxSupport does not have this tilting possibility. Various accessories are provided for positioning of the arms or the thorax.

For the ThoraxSupport a glassfiber MR alternative (Thoraxsupport MR) is available for identical lung and thorax positioning in MR environment. The MR safe device has a 3Pin slot on the bottomside and is compatible with the glassfiber 3Pin CouchStrip. The MR unsafe devices are not compatible with the 3Pin MR safe CouchStrip, which prevents the use in the wrong environment.

MacroMedics Devices	Predicate devices:	510(k) number:
BreastBoard LX	Sinmed Posiboard	K060737 (IYE)
ThoraxSupport	Sinmed Posirest	K060737 (IYE)
ThoraxSupport MR	Sinmed Posirest	K060737 (IYE) K093738 (LNH, reference device)

Lung- and thorax positioning systems (2/2)

Comparision of technological characteristics:

The designs of the MacroMedics and predicate lung and thorax positioning systems are equivalent in shape, construction, materials and functionality.
Both the Sinmed devices and the MacroMedics devices are made out of carbon fiber with components of plastic, aluminium and foam. MacroMedics uses glass fiber for the MR safe alternative of the ThoraxSupport. Both the biocompatibility and the MR safety of these new materials have been described in this 510(k).

Substantial equivalence summary:

MacroMedics claims the proposed lung and thorax positioning systems 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, patient positioning and used materials. Although small technological differences exist, these products have similar position and immobilization characteristics for use radiotherapy and radio-diagnostics.

Conclusions:

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. The biological safety evaluation and the MR safety evaluation have supported the claim of safety when used in an MR environment and in contact the patient's skin.

Pelvic and lower extremities positioning systems (1/2)

Pelvic Prone Board
Pelvic Prone Board MR
LEPS

Intended use / Indications for use:

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

Device description:

Baseplates which are designed to position the pelvic or (lower) extremities of a patient. The Pelvic Prone Board positions the patient in prone position with the arms in cranial direction, belly is placed in an aperture. The shape of the pelvic prone board moves the small bowel and reduces the irradiated small bowel volume while treating the lower abdomen.
The LEPS position the legs on a KneeSupport which can be tilted and the feet are positioned in a FeetSupport. Both baseplates can be positioned on the couch using fixation rails.

For the Pelvic Prone Board a glassfiber MR alternative (Pelvic Prone Board MR) is available for identical positioning in MR environment. The LEPS is a MR safe device. The MR safe devices have 3Pin slots on the bottomside and are compatible with the glassfiber 3Pin CouchStrip. The MR unsafe device is not compatible with the 3Pin MR safe CouchStrip, which prevents the use in the wrong environment.

MacroMedics Devices	Predicate	510(k) number:
Pelvic Prone Board	Sinmed Bellyboard	K060737 (IYE)
Pelvic Prone Board MR	Sinmed Bellyboard	K060737 (IYE) K121545 (LNH & IYE, reference device)
LEPS	Sinmed Combifix	K060737(IYE) K093738 (LNH, reference device)

Pelvic and lower extremities positioning systems (2/2)

Comparision of technological characteristics:

The designs of the MacroMedics and predicate pelvic and lower extremities positioning systems are equivalent in shape, construction, materials and functionality.
Both the Sinmed devices and the MacroMedics devices are made out of carbon fiber with components of plastic and foam. MacroMedics uses glass fiber for the MR safe alternative of the Pelvic Prone Board. Both the biocompatibility and the MR safety of this different material have been described in this 510(k).

Substantial equivalence summary:

MacroMedics claims the pelvic and lower extremities positioning systems 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, patient positioning and used materials. Although small technological differences exist, these products have similar position and immobilization characteristics for use radiotherapy and radio-diagnostics.

Conclusions:

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. The biological safety evaluation and the MR safety evaluation have supported the claim of safety when used in an MR environment and in contact the patient's skin.

SBRT systems (1/2)

SBRT EAMIS
SBRT EAMIS Lite
SBRT OmniBoard (UATB)
SBRT MultiBoard (UTB)
SBRT MultiFrame (UTF)
VacuumCushions
CouchStrips

Intended use / Indications for use:

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

Device description:

The SBRT systems (Stereotactic Body Radiation Therapy Systems) are devices which can position various bodyparts of the patient. The MacroMedics SBRT systems are carbon fiber baseplates over which various plastic bridges can be placed with attached accessories to position the patient's body. The SBRT OmniBoard does have an inclination possibility of the upper body. The accessories are identical, but the baseboards are different, each baseboard has slightly different features for customer preferences. The patient set-up is similar on all boards, supine position with the arms mainly positioned above the patient's head. Bottom, knees and feet positioned in indexed positions.

Vacuumcushions are used for positioning by moulding the cushion around the patients and then take the air out with a vacuumpump. The contrashape of the patient stays in the cushion during the treatment.
CouchStrips are strips which connect the patient positioning device onto the couch at indexed positions. Depending on the indexing system of the couch, width of the couch, preference in transverse adjustability and required MR safety different types are available.
The SBRT carbon fiber baseplates are MR unsafe and have a 2Pin CouchStrip slot. They are not compatible with the 3Pin MR CouchStrip, which prevents the use in the wrong environment.
The CouchStrips for MR are made out of MR safe materials and have 3pins. MR unsafe devices have a 2Pin CouchStrip slot on the bottomside and are not compatible with this 3Pin MR CouchStrip.
The Vacuumcushions are MR safe.

MacroMedics Devices	Predicate devices:	510(k) number:
SBRT EAMIS	CIVCO Body Pro Lok	K111340 (LNH & IYE)
SBRT OmniBoard (UATB)	CIVCO Body Pro Lok	K111340 (LNH & IYE)
SBRT MultiBoard (UTB)	CIVCO Body Pro Lok	K111340 (LNH & IYE)
SBRT MultiFrame (UTF)	CIVCO Body Pro Lok	K111340 (LNH & IYE)
SBRT EAMIS Lite	CIVCO Rails-Only System	K111340 (LNH & IYE)
CouchStrips	CIVCO LokBar	K111340 (LNH & IYE)
VacuumCushions	Sinmed Repovac Cushions	K060737 (IYE) K093738 (LNH, reference device)

SBRT systems (2/2)

Comparision of technological characteristics:

The designs of the MacroMedics and predicate SBRT positioning systems are equivalent in construction, accessories, materials and functionality. Both the predicate and the MacroMedics SBRT devices are made out of carbon fiber baseplates with bridges of plastic which clamp on the sides of the baseplates, foam head- knee and FeetSupports can be placed at indexed positions. MacroMedics and Sinmed vacuum cushions are both constructed with a small polystyrene bullets in a nylon bag and a valve for creating vacuum.
MacroMedics CouchStrips and the CIVCO LokBars have similar designs, almost identical dimensions and materials. MacroMedics added a carbon fiber alternative for its good mechanical and dosimetric properties.

Substantial equivalence summary:

MacroMedics claims the proposed SBRT systems 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, patient positioning and used materials. Although small technological differences exist, these products have similar position and immobilization characteristics for use radiotherapy and radio-diagnostics.

Conclusions:

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. The biological safety evaluation and the MR safety evaluation have supported the claim of safety when used in an MR environment and in contact the patient's skin.

Thermoplastic positioning systems (1/2)

Thermoplastics various sizes and profiles
DSPS & SSPS thermoplastic masks
DSPS & SSPS cradles

Intended use / Indications for use:

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

Device description:

MacroMedics thermoplastic masks are developed in order to position the individual patient. The thermoplastic masks are placed in a waterbath of about 70 degrees where they become flexible. After drying and cooling, they make a perfect contramould of the bodypart which needs to be positioned. Plastic profiles attach the mask onto the baseplate. Masks and profiles are available in many different shapes, in order to fit on different baseplates and bodyparts.
DSPS offers a possibility to create a thermoplastic mask for both occipital- and facial areas for extra accurate positioning. Both masks are attached onto the DSPS cradle, and the DSPS cradle is attached onto the baseplate.
MacroMedics thermoplastic masks with plastic profiles are MR safe.

MacroMedics devices	Predicate devices:	510(k) number:
Thermoplastics various sizes and profiles	Sinmed Posicast immobilization system	K060737 (IYE) K093738 (LNH, reference device)
DSPS & SSPS thermoplastic masks	CIVCO head immobilization plastics	K080072 (IYE) K093738 (LNH, reference device)

Thermoplastic positioning systems (2/2)

Comparision of technological characteristics:

The designs of the MacroMedics and predicate systems are equivalent in construction, design, materials and functionality. Both the predicate and the MacroMedics masks are made out of thermoplastics which are cut in shape and glued or welded into plastic injection moulded profiles. Both thermoplastic masks become soft in warm water and make a contrashape of the patient and are connected onto a baseplate, where they become a rigid patient positioning device after cooling. The DSPS cradle is made out of a carbon fiber construction and can be positioned on the baseplate. With the DSPS both a facial and occipital contrashape can be moulded and fixed. The predicate Medtec and CIVCO devices provide a similar occipital moulding possibility.

Substantial equivalence summary:

MacroMedics claims the proposed thermoplastic positioning systems 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, product handling, patient positioning and used materials. Although small technological differences exist, these products have similar position and immobilization characteristics for use radiotherapy and radio-diagnostics.

Conclusions:

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. The biological safety evaluation and the MR safety evaluation have supported the claim of safety when used in an MR environment and in contact the patient's skin.