Essebi Medical SRL
℅ Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL MN 55114

April 30, 2019

Re: K190894
Trade/Device Name: TOTIM Patient Cushion Immobilization System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: April 4, 2019
Received: April 5, 2019

Dear Mr. Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190894

Device Name
TOTIM Patient Cushion Immobilization System

Indications for Use *(Describe)*

The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the body, head, brain, and neck, including Stereotactic Radiosurgery (SRS), Stereotactic Radiotherapy (SRT), Surface Guided Radiation Therapy (SGRT) and electron, photon, and proton treatments. The device is also used during image acquisition, including Computed Tomography (CT), Magnetic Resonance (MR) Imaging, to support treatment planning.

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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TOTIM®
TOTALLY - IMMOBILE
immobilization system in radiotherapy

CE Direttiva CEE 93/42 Dispositivo Medico Directive EEC 93/42 Medical Device
Dispositivo Medico di Classe I
Medical Device Class I

Section 5 - 51O(k) Summary K190894

A. Submitter Information

Submitter Name & Address: ESSEBI MEDICAL SRL
Strada Campo del Fiume 84
47896 Faetano
Repubblica di San Marino

Contact Person: Pietro Sordina, President and Chief Executive Officer
Telephone: 00378-0549-963858
p.sordina@totim.it

Date Summary Prepared: January 22, 2019

Trade Name: TOTIM® Patient Cushion Immobilization System
Common Name: Patient Cushion
Classification Names & Numbers: Medical charged-particle radiation therapy system Accelerator, Linear, Medical (892.5050)
Nuclear Magnetic Resonance Imaging (892.1000)
Device Class: Class II
Review Panels: Radiology
Product Codes: IYE

B. Predicate Device

The proposed device is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer
RediFoam™ two-part positioning foam RediFoam for verifiable repositioning throughout treatment. (K951808)	MEDTEC, Inc.

The purpose of this 510(k) is to 1) release new SRS/SRT/SGRT compatible system, and 2) identify intended use statements for the proposed device. ESSEBI MEDICAL has not submitted any prior submissions for the proposed device.

C. Device Descriptions

TOTIM is a fully sealed, polyurethane foam cushion covered with microfiber polyester tissue for patient positioning and immobilization during simulation, planning and radiation treatment. The cushion shapes and molds around the patient after activation of the internal components. It maintains its formed shape during all sessions of radiotherapy treatment, enabling reproducibility of patient position. The device is molded at the back of the patient's body, parts of the body or the head in order to hinder the usual range of movement occurring with non-customizable supports.

ESSEBI MEDICAL Srl
Strada Campo del Fiume 84 Faetano 47896 Repubblica di San Marino C.O.E. SM26889 Tel. +378 0549 963858
www.totim.it e-mail: info@totim.it PEC: totim@pec.totim.it – Registro impresa n. 7577

Construction Features: Cushion: External Cover Microfiber polyester / PU (fully sealed) - Internal pouch (fully sealed): PE/AL/PET humidity-resistant pouch containing two reagents ready to be mixed.
Technical Characteristics: Cushion with external cover in microfiber comfortable and absorbent water repellent non-woven material, washable/easily sanitized- temperature controlled exothermic reaction- the short window of time required for solidification allows for the correct modeling of the external cover in microfiber polyester tissue fully sealed. Single-patient /single-use - Latex Free - Radiotransparent - MR safe.

Patent Pending: SM P-201700411
IT 102017000098840
UE 18000703.1 8
U.S. 16/117,817

The TOTIM® Patient Cushions Immobilization System device is manufactured of non-magnetic materials. The device is used in a healthcare facility/hospital. The device is intended to be used on adult and pediatric patients. The following model is included in this submission:

Device Family	**Part No.**	**Device Name**
Patient Cushion Immobilization System	T3001 TTM3001	TOTIM BODY L

D. Indications for Use/Intended Use Statements

Indications for Use:

TOTIM® Patient Cushion Immobilization System is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the body or the head, brain, and neck, including Surface Guided Radiation Therapy (SGRT) and electron, photon, and proton treatments. The device is also used during image acquisition, including Computed Tomography (CT) Magnetic Resonance (MR) Imaging, to support treatment planning.
System Intended Use: The device is part of a system intended to immobilize, position and reposition patients undergoing radiation therapy including SBRT.

Device- Specific Intended Use:

The device maintains its formed shape during all sessions of radiotherapy treatment, enabling reproducibility of patient position. The device is molded at the back of the patient's body, parts of the body or the head in order to hinder the usual range of movement occurring with non-customizable supports.

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E. Comparison of Technological Characteristics

Technological characteristics that have changed between the proposed and predicate device include changes in design and materials and in safety use with cushion fully sealed . The proposed TOTIM Patient Cushion device have been proven to reduce preparation time, especially for difficult set-ups. The TOTIM cushion proposed compared to the predicate product are improving because the polyester microfiber cushion coupled to the internal PU film is a cushion closed fully sealed. Inside the cushion there is a fully sealed pouch with two separate components ready to be used to produce the polyurethane foam. The advantages of having a closed system for both the external bag and the inner pouch allows operators greater safety and easy to use. With Totim we eliminate the risk of the foam out of the outer bag, make the use more practical, less risk and fast because the components are already inside the pouch contained in the fully sealed closed bag. Furthermore, the cushion with respect to the predicate product being made of a microfiber is more comfortable for the patient. The fabric of the cushion coupled with the internal PU film allows perfect adherence to the foam being both polyurethane products obtaining a unique and compact end-product.

#	Feature	Predicate Device (RediFoam™ Two-part positioning foam)	ESSEBI MEDICAL Device (TOTIM® Patient Cushion immobilization system)
1	Indications for Use	RediFoam™ - The device is indicated to position and/or immobilize adult. Is indicated to assist in the proper positioning of patients for radiation therapy and radiosurgery simulation.	The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the body or the head, brain, and neck, including Surface Guided Radiation Therapy (SGRT) and electron, photon, and proton treatments. The device is also used during image acquisition, including Computed Tomography (CT) Magnetic Resonance (MR) Imaging, to support treatment planning.
2	Classification	Class II (K951808)	Class II
3	Features	Polyurethane foam immobilization system using open bag.	Polyurethane foam immobilization system using fully sealed bag/cushion. System can be attached to the treatment or simulation couch, extension, or overlay along with other optional positioning and immobilization devices and accessories.

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#	Feature	Predicate Device (RediFoam™ Two-part positioning foam)	ESSEBI MEDICAL Device (TOTIM® Patient Cushion Immobilization System)
4	Materials	Bag in Polyethylene film 2 Bottle Polyurethane: bottle#1– bottle#2	Cushion: Microfiber polyester / PU fully sealed Internal pouch: PE/AL/PET Internal pouch fully sealed with 2 pockets: Polyurethane
5	Device Body Contact Category	Unknown	Limited contact duration (<24 hours) for surface devices (skin)
6	Immobilization	Unknown	The cushion system can reproduce the patient position within a treatment cycle: SRS/SRT,SGRT, MRI, ELETRON, PHOTON, PROTON and PROTON treatments
7	Performance	Unknown	SRS/SRT, SGRT, MRI

F. Non-Clinical Testing

Non-clinical testing was completed to confirm that the proposed device is as safe and effective as the predicate device and to confirm that the changes in technological characteristics do not raise any new issues of safety or effectiveness.
A scientific rationale was used to address RF heating, magnetically induced torque, and magnetically induced displacement force.
The TOTIM device was tested with ASTM F2119-07 (Reapproved 2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants (Materials), TOTIM is MR Safe.
The devices are intended for limited contact duration (<24 hours) for surface devices (skin). Biocompatibility testing was completed for patient-contacting materials in accordance with ISO 10993-5:2009, 10993-12: 2012 and ISO 10993-10: 2010.
Declaration of Conformity 93/42/CEE Medical Device Class I

G. Conclusion

This premarket submission for the TOTIM® Patient Cushion Immobilization System of polyurethane foam to be used in radiotherapy for repeated positioning of the patient has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

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