DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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MEDTEC, Inc. d/b/a CIVCO Medical Solutions
% Ms. Amanda Stahle
Regulatory Affairs Specialist
1401 8th Street SE
ORANGE CITY IA 51041

May 25, 2016

Re: K153026
Trade/Device Name: Body Pro-Lok™ Respiratory Plate with Cushion, Body Pro Lok™ Respiratory Belt
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, LNH
Dated: May 20, 2016
Received: May 23, 2016

Dear Ms. Stahle:

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,

Robert Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153026

Device Name
Respiratory Plate with Cushion; Respiratory Belt

Indications for Use *(Describe)*
The device is indicated to assist in the proper positioning of patients for radiation therapy including electron, photon and proton treatments, and simulation including CT and MR image acquisition.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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WWW.CIVCO.COM

Section 5 – 510(k) Summary

A. Submitter Information

Submitter Name & Address:	MEDTEC, Inc. d/b/a CIVCO Medical Solutions 1401 8th St. SE Orange City, IA 51041
Contact Person:	Amanda Stahle, Regulatory Affairs Specialist Telephone: 319-248-6628, Fax: 877-218-0324 amanda.stahle@civco.com
Date Summary Prepared:	October 14, 2015
Trade Name:	Body Pro-Lok™ Respiratory Plate with Cushion; Body Pro-Lok™ Respiratory Belt
Common Name:	Respiratory Plate with Cushion; Respiratory Belt
Classification Names & Numbers:	Medical charged-particle radiation therapy system (892.5050) System, Nuclear Magnetic Resonance Imaging (892.1000)
Device Class:	Class II
Review Panels:	Radiology
Product Codes:	IYE, LNH

B. Predicate Devices

The proposed devices are substantially equivalent to the following predicate devices:

Predicate Devices	Manufacturer
Compression Bridge and Compression Belt included in CDR Systems Precision Patient Positioning System (K122888)	CDR Systems, Inc.

The purpose of this 510(k) is to 1) modify the design of the Respiratory Plate by attaching an inflatable Cushion, 2) expand the indications for use of the Respiratory Belt to include use in the MR environment, and 3) identify intended use statements for the proposed devices.

C. Device Descriptions

The Respiratory Plate with Cushion and Respiratory Belt are components of a modular-based patient positioning system that indexes directly to a treatment or simulation couch.

The Respiratory Plate is comprised of a compression plate, mount, index screw, and screw wheel. Rotation of the screw wheel lowers and raises the compression plate. The mount is attached to the positioning system bridge using pins, and the bridge is indexed to the

system platform using a clamping mechanism. A Cushion is mounted on the compression plate via pocket features on the Cushion. The Cushion is comprised of three compartments of beads plus an air chamber. The Cushion is inflated with air to the desired pressure using a hand-held pump accessory with reference pressure gauge.

The Respiratory Belt is comprised of a central air chamber with indexing scale, Velcro straps, hand pump, pressure gauge, and clamps. The Velcro straps allow the Belt to be tightened or loosened around the patient. The Belt is inflated using a hand pump and the pressure is monitored with a reference pressure gauge. Clamps are used to attach the Velcro straps to the positioning system platform.

The Respiratory Plate with Cushion and Respiratory Belt are reusable devices that are provided non-sterile and are manufactured of non-magnetic materials with the exception of the pressure gauge. The devices are used in a healthcare facility/hospital. The following models are included in this submission:

Device Family	**Part No.**	**Device Name**
Respiratory Plate with Cushion	BPL007	Respiratory Plate Cushion
	BPL008	Respiratory Plate, Wide
Respiratory Belt	MTSBRT004	Respiratory Belt
	BPL002	Respiratory Belt
	BPL006	Rail Clamp for Respiratory Belt
	MTSBRT035	Pressure Gauge Replacement

D. Indications for Use/Intended Use Statements

Indications for Use: The device is indicated to assist in the proper positioning of patients for radiation therapy including electron, photon and proton treatments, and simulation including CT and MR image acquisition.

System Intended Use: The device is part of a system intended to immobilize, position and reposition patients undergoing stereotactic radiation therapy including SBRT.

Device-Specific Intended Use: The device is intended to apply abdominal compression for managing movement and tumor motion during respiration while maintaining maximum comfort to the patient.

E. Comparison of Technological Characteristics

Technological characteristics that have changed between the proposed and predicate devices include changes in design and materials. Both the proposed Respiratory Plate with Cushion and predicate device consist of an abdominal compression plate indexed to a system bridge, but the proposed device also includes a cushion mounted to the compression plate. Both the proposed Respiratory Belt and predicate device are pneumatic abdominal respiratory belts with Velcro straps to tighten and secure the device around the patient, but the proposed device attaches to the system platform whereas the predicate device is free-standing. Different materials were used to manufacture the proposed devices and were selected with MR safety and effectiveness considerations.

F. Non-Clinical Testing and Literature Review

Non-clinical testing was completed to confirm that the proposed devices are as safe and effective as the predicate devices and to confirm that the changes in technological characteristics do not raise any new issues of safety or effectiveness. For the Respiratory Plate with Cushion, a scientific rationale was used to address RF heating, magnetically induced torque, and magnetically induced displacement force. The Respiratory Plate with Cushion was tested for image artifact using ASTM Standard F2119-07 as guidance. No artifact was observed.

The Respiratory Belt was tested for MR safety and compatibility in accordance with ASTM Standards F2182-11a, F2052-14, and F2213-06, and was also tested using ASTM Standard F2119-07 as guidance. The Respiratory Belt passed the acceptance criteria for RF heating, magnetically induced torque, and magnetically induced displacement force and demonstrate that the device is safe for use in field strengths of 1.5 T and 3.0 T. Image artifact was observed near the pressure gauge and BPL002 clamp component, and information regarding size of each artifact has been included in the Instructions for Use.

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 and ISO 10993-10.

A literature review was conducted to support the intended use statements. The literature demonstrates that these devices are safely and effectively used in applying abdominal compression for managing movement and tumor motion during respiration.

G. Conclusion

This premarket submission for the Respiratory Plate with Cushion and Respiratory Belt 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.