



MEDTEC Inc. dba CIVCO MEDICAL SOLUTIONS
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO, MN 55313

September 7, 2018

Re: K182079

Trade/Device Name: Solstice™ SRS Immobilization System; Solstat™ Immobilization System;
Solstice™ Thermoplastic Mask

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: Class II

Product Code: IYE, LNH

Dated: July 31, 2018

Received: August 2, 2018

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.

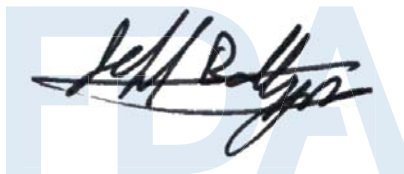
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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

Enclosure

Indications for Use

510(k) Number (if known)

K182079

Device Name

(1 & 2) Solstice™ SRS Immobilization System

(3) Solstat™ Immobilization System ; Solstice™ Thermoplastic Mask

Indications for Use (Describe)

1. Solstice™ SRS Immobilization System (when used with customizable cushion):

The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the 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), to support treatment planning.

2. Solstice™ SRS Immobilization System (when used with headrest):

The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of 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), to support treatment planning.

3. Solstat™ Immobilization System & Solstice™ Thermoplastic Mask:

The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Section 5 – 510(k) Summary

A. Submitter Information

Submitter Name & Address: MEDTEC, Inc.
d/b/a CIVCO Medical Solutions and CIVCO Radiotherapy
1401 8th St. SE
Orange City, IA 51041

Contact Person: Alena Newgren, Regulatory Specialist
Telephone: 319-248-6650, Fax: 877-613-6300
alena.newgren@civcort.com

Date Summary Prepared: May 21, 2018

Trade Name: Solstice™ SRS Immobilization System; Solstat™ Immobilization System; Solstice™ Thermoplastic Mask

Common Name: Tilting Head Fixation System; Static Head Fixation System; Open-Face Thermoplastic Mask

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 |
|--|-------------------|
| Systems Prone Head and Neck Immobilization System included in CDR Systems Precision Patient Positioning System (K122888) | CDR Systems, Inc. |

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

C. Device Descriptions

The Tilting Head Fixation (Solstice) device is comprised of a baseplate and bowl with a locking lever. The bowl is permanently attached to the baseplate and the locking level

www.CivcoRT.com

Corporate Office | 2303 Jones Boulevard Suite B | Coralville, IA 52241 | USA | office +1 (319) 248.6757 | info@CivcoRT.com

Global Sales Office | 1401 8th Street SE | Orange City, IA 51041 | USA | office +1 (712) 737.8688 | fax +1 (877) 613.6300



allows the bowl to be tilted up to 10° in relation to the baseplate at infinite intervals. The baseplate is attached to the treatment or simulation couch top or overlay by pins. When used with customizable cushion and thermoplastic mask, the system can immobilize the patient to under 1 millimeters. The provider can correct the patient position for simulation and treatments by tilting the device.

The Static Head Fixation (Solstat) device is comprised of a baseplate and bowl with a locking lever. The bowl is permanently attached to the baseplate and cannot be tilted. The baseplate is attached to the treatment or simulation couch top or overlay by pins. When used with customizable cushion and thermoplastic mask, the system can reproduce the patient position to under 3 millimeters within a treatment cycle.

The Open-Face Thermoplastic mask is comprised of a thermoplastic mask bonded with a frame. The frame has five swivel clamps that allow secure attachment onto either the Solstice or Solstat device. When heated, the thermoplastic mask can be formed around the patient anatomy and allows the Region of Interest (ROI) to be capture by camera systems, allowing Surface Guided Radiation Therapy to occur via camera systems. The same mask will be used throughout the course of the treatment. The Open-Face style mask is ideal for Surface Guided Radiation Therapy (SGRT) via camera systems.

The Solstice Immobilization device and Solstat Immobilization device are reusable devices that are provided non-sterile. Solstat and Solstice thermoplastic are single-patient reusable and is provided non-sterile and manufactured of non-magnetic materials. The devices are used in a healthcare facility/hospital. All devices are intended to be used on adult and pediatric patients. The following models are included in this submission:

| Device Family | Part No. | Device Name |
|------------------------------|---------------|---|
| Tilting Head Fixation System | CHS03 | Solstice SRS Immobilization System with Type-S Base |
| | CHS04 | Solstice SRS Immobilization System with Posi Style Base |
| Static Head Fixation System | CHS05 | Solstat Immobilization System with Type-S Base |
| | CHS06 | Solstat Immobilization System with Posi Style Base |
| Open Face Thermoplastic Mask | MTAPCIN1832SG | Thermoplastic Mask, Standard Frame, Open Face |
| | MTAPCIN1832SG | Thermoplastic Mask, Narrow Frame, Open Face |

www.CivcoRT.com

Corporate Office | 2303 Jones Boulevard Suite B | Coralville, IA 52241 | USA | office +1 (319) 248.6757 | info@CivcoRT.com

Global Sales Office | 1401 8th Street SE | Orange City, IA 51041 | USA | office +1 (712) 737.8688 | fax +1 (877) 613.6300



D. Indications for Use/Intended Use Statements

Indications for Use:

Solstice™ SRS Head Immobilization System (when used with customizable cushion):

The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the 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), to support treatment planning.

Solstice™ Head Immobilization System (when used with headrest):

The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of 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), to support treatment planning.

Solstat Head Immobilization System and Open-Face Thermoplastic Mask:

The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of 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.

Device-Specific Intended Use:

Solstice SRS Head Immobilization:

The device is intended to immobilize the patient by encapsulating the head and provide corrective tilting of the head for treatment and simulation.

Solstat Head Immobilization System and Open-Face Thermoplastic Mask:

The device is intended to immobilize the patient by encapsulating the head for treatment and simulation such as MRI.

E. Comparison of Technological Characteristics

Technological characteristics that have changed between the proposed and predicate devices include changes in design and materials. The proposed Solstice Tilting Head Fixation System and predicate allow SRS/SRT and use headrests and thermoplastic masks, but the proposed Tilting device allows for infinitely adjustable angles from -5° to +5°, either used with customizable cushion (for SRS/SRT) or reusable headrest, and open-face mask to be used with camera systems and SGRT. Both the Solstat Static Head Fixation System and predicate system allow for patient immobilization, but the proposed device allows for use of customizable cushion and open-face mask to be used with camera

www.CivcoRT.com

Corporate Office | 2303 Jones Boulevard Suite B | Coralville, IA 52241 | USA | office +1 (319) 248.6757 | info@CivcoRT.com

Global Sales Office | 1401 8th Street SE | Orange City, IA 51041 | USA | office +1 (712) 737.8688 | fax +1 (877) 613.6300



systems and surface guided radiation therapy(SGRT). Different materials were used to manufacture the proposed devices and were selected with MR safety and effectiveness considerations.

| # | Feature | Predicate Device (CDR Systems Prone Head and Neck Immobilization System) | CIVCO Device (Solstice SRS Immobilization System) | CIVCO Device (Solstat Immobilization System and Open-Face Thermoplastic Mask) |
|---|---------------------|---|---|---|
| 1 | Indications for Use | CDR Systems Precision Patient Positioning System is indicated to assist in the proper positioning of patients for radiation therapy and radiosurgery simulation and treatment including electron, photon and proton treatments. Place a clean sheet over the device to ensure a clean device from patient to patient. | <p><u>Tilting Head Immobilization System (when used with customizable cushion):</u> The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the 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), to support treatment planning.</p> <p><u>Tilting Head Immobilization System (when used with headrest):</u> The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of 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), to support treatment planning.</p> | The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of 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 (K122888) | Class II | Class II |
| 3 | Features | A headboard that attaches to a baseplate that locates onto a couch tabletop, onto a CDR | The Tilting Head Fixation System can be attached to the treatment or simulation | The Static Head Fixation System can be attached to the treatment or simulation |

www.CivcoRT.com

Corporate Office | 2303 Jones Boulevard Suite B | Coralville, IA 52241 | USA | office +1 (319) 248.6757 | info@CivcoRT.com

Global Sales Office | 1401 8th Street SE | Orange City, IA 51041 | USA | office +1 (712) 737.8688 | fax +1 (877) 613.6300

| # | Feature | Predicate Device (CDR Systems Prone Head and Neck Immobilization System) | CIVCO Device (Solstice SRS Immobilization System) | CIVCO Device (Solstat Immobilization System and Open-Face Thermoplastic Mask) |
|---|------------------------------|--|---|---|
| | | Couch Overlay or Couch Extension and provides adjustable positive and negative tilt for patient's head. Can be used for support of a patient's head in supine or prone position. A low temperature thermoplastic mask can be used for additional immobilization. | couch, extension, or overlay along with other optional positioning and immobilization devices and accessories. The thermoplastic mask is attached onto the device and is molded to the patient's facial anatomy. The patient lies directly on the treatment surface in the supine position. | couch, extension, or overlay along with other optional positioning and immobilization devices and accessories. The thermoplastic mask is attached onto the device and is molded to the patient's facial anatomy. The patient lies directly on the treatment surface in the supine position. |
| 4 | Materials | Carbon fiber/epoxy laminate material with foam core. MR Safe – Kevlar/epoxy laminate material with foam core. | Carbon Fiber, Black Acetal, Kydex-T, Nylon, Polycarbonate | <u>Static Head Fixation(MR):</u> Kydex-T, Nylon, Polycarbonate <u>Thermoplastic Mask(MR):</u> Polycaprolactone, Polycarbonate |
| 5 | Device Body Contact Category | Limited contact duration (<24 hours) for surface devices (skin). | Limited contact duration (<24 hours) for surface devices (skin). | Limited contact duration (<24 hours) for surface devices (skin). |
| 6 | Immobilization | SRS/SRT (marketing) | When used with customizable cushion and thermoplastic mask, the system can immobilize the patient to under 1 millimeter(SRS/SRT). | When used with customizable cushion and thermoplastic mask, the system can reproduce the patient position to under 3 millimeters within a treatment cycle. |
| 7 | Performance | SRS/SRT, MR | SRS/SRT, SGRT, Adult & Pediatrics | MRI, SGRT, Adult & Pediatrics |

F. Non-Clinical Testing

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 Solstat Device, a scientific rationale was used to address RF heating, magnetically induced torque, and magnetically induced displacement force. The Solstat device was tested for image artifact using ASTM Standard F2119-07 as guidance and is considered MR Safe.

www.CivcoRT.com

Corporate Office | 2303 Jones Boulevard Suite B | Coralville, IA 52241 | USA | office +1 (319) 248.6757 | info@CivcoRT.com

Global Sales Office | 1401 8th Street SE | Orange City, IA 51041 | USA | office +1 (712) 737.8688 | fax +1 (877) 613.6300



For the Solstice Device, non-clinical testing using camera systems was done to substantiate the use for Stereotactic Radiosurgery (SRS) and Stereotactic Radiotherapy (SRT). Based on data obtained we can state that intrafraction movement during a 5-minute scanning window to the 99.73% Confidence Interval is less than 1.000mm. Additionally, based on the data obtained, we can state that intrafraction movement during a 30 minute scanning the 95.45% confidence intervals is less than 1mm.

Therefore, the Tilting Head Fixation System appropriately immobilizes a patient for SRS/SRT such that the intrafractional shifts are less than 1mm within a 5-minute window with 99.73% confidence, and within a 30-minute window with 95.45% confidence.

Based on testing with VisionRT's AlignRT system, Solstice, Solstat, and the Open-Face thermoplastic mask can be used for Surface Guided Radiation Therapy (SGRT) as the Region of Interest (ROI) is able to be seen by the camera system.

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.

G. Conclusion

This premarket submission for the Tilting Head Fixation System, Static Head Fixation System, and Open-Face Thermoplastic Mask 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.

www.CivcoRT.com

Corporate Office | 2303 Jones Boulevard Suite B | Coralville, IA 52241 | USA | office +1 (319) 248.6757 | info@CivcoRT.com

Global Sales Office | 1401 8th Street SE | Orange City, IA 51041 | USA | office +1 (712) 737.8688 | fax +1 (877) 613.6300