



MAR 04 2014

K132908
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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
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Date Summary Prepared: January 20, 2014

Trade Name: trUpoint ARCH™
Common Name: Head Immobilization System
Classification Names: System, Nuclear Magnetic Resonance Imaging
Accelerator, Linear, Medical
Classification Numbers: Class II under 21 CFR 892.1000 & 892.5050
Review Panels: Radiology
Product Codes: LNH & IYE

B. Predicate Device

The proposed Head Immobilization System is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer
K982019: Med-Tec Head Immobilization System	Med-Tec, Inc.
K112210: Fraxion™	Medical Intelligence Medizintechnik GmbH

The purpose of this 510(k) is to expand the indications for use to include use in the MR environment. CIVCO has conducted MR safety and compatibility testing to confirm that the proposed device and accessories can be safely used in the MR environment.

C. Device Description

The Head Immobilization System is intended for head and neck immobilization. The device is used as an aid in positioning and re-positioning of the patient during diagnostic and therapeutic treatments including radiation therapy. The fundamental component of the system is the trUpoint ARCH™ comprised of an arch, frame arm, bite assembly arm, and nasion assembly arm. A nasion cushion and bite cup also comprise the system. A storage plate is used to store the trUpoint ARCH™ and a Base Lock Replacement Kit is

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available to replace the base lock in the trUpoint ARCH™. Accessories to the proposed device that are manufactured by CIVCO Medical Solutions include the individual head support, thermoplastic mask, and baseplate. Accessories to the proposed device that not manufactured by CIVCO Medical Solutions include a bite tray, impression putty, and putty dispenser.

The proposed devices are sold non-sterile. The nasion cushion and bite cup are single patient use devices whereas the trUpoint ARCH™ may be reused for multiple patients. The proposed devices are non-implanted devices that are large in size and manufactured of non-magnetic and plastic materials. The Head Immobilization System consists of the following models:

Part No.	Device Name
MTHF01	trUpoint ARCH™
MTHF016	Nasion Cushion
MTHF135	Bite Cup
MTHF300	trUpoint ARCH™ Storage Plate
MTHF01-LK	trUpoint ARCH™ Base Lock Replacement Kit

D. Indications for Use/Intended Use

The device is intended to be used for immobilization, positioning and re-positioning during Stereotactic Radiotherapy (SRT) and Stereotactic Radiosurgery (SRS) in all parts of the brain, head, and neck during external beam radiation therapy. The device is also used to immobilize and position the head during image acquisition to support treatment planning including in Computed Tomography (CT) and Magnetic Resonance (MR) imaging systems.

E. Technological Characteristics and Indications for Use Comparison

Technological characteristics that have changed between the proposed device and Med-Tec Head Immobilization System (K982019) predicate device include changes in design and materials. The design changes include the addition of a frame arm that extends perpendicularly from the arch and holds the bite and nasion assemblies. The angles of the nasion and bite assemblies are now adjustable with indexing. The bite assembly is standard in the proposed device and provides further immobilization of the head in conjunction with bite tray and impression putty accessories. The head support and thermoplastic mask continue to serve as accessories to the system, and these accessories and the proposed device attach to a baseplate. Additional materials were used to manufacture the proposed device and were selected with MR safety considerations. The indications for use/intended use of the proposed device will include use in the MR environment and will specify use during Stereotactic Radiotherapy (SRT) and Stereotactic Radiosurgery (SRS).

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The technological differences between the proposed device and the Fraxion™ (K112210) predicate device include differences in design and materials. Both devices feature a frame as the fundamental component, but on the Fraxion™ device a frontpiece completes the arch over the patient and this frontpiece directly receives the mouthpiece. On the proposed device, a frame arm extends perpendicularly from the arch from which a second arm extends and receives the bite cup and bite tray. In both devices a dental impression is created using putty, but on the Fraxion™ device this is secured to the mouthpiece using adhesive whereas on the proposed device the dental impression is formed directly to the bite tray. In the Fraxion™ device, the mouthpiece is fixed to the patient's maxilla using a vacuum. A patient control unit provides this vacuum and delivers an alert when the mouthpiece is loosened. The proposed device features a nasion cushion positioned snugly against the patient's nose. Both devices work with a cushion (head support) under the patient's head and a thermoplastic mask to provide immobilization over the head. A stereotactic frame with fiducials is utilized as part of the Fraxion™ system.

The Fraxion™ device is comprised of carbon fiber whereas the materials that comprise the proposed device were selected with MR safety considerations. The indications for use/intended use of the Fraxion™ predicate device does not specify use in the MR environment. Otherwise the indications for use of the Fraxion™ predicate are substantially similar to that of the proposed device including immobilization, positioning, and re-positioning of the head during SRT and SRS in a linear accelerator environment. Both devices are also used to immobilize and position the head during image acquisition to support treatment planning.

F. Non-Clinical Testing and White Paper on European Site Testing

CIVCO has conducted non-clinical testing to demonstrate that the design and materials do not affect the safety and effectiveness of the device in the MR environment. MR compatibility test methodology generally followed ASTM Standards F2182-11a, F2119-07, F2052-06e1 and F2213-06, but modifications were made to accommodate the large size of several of the proposed devices and to accommodate their external use (not implanted). The devices passed the acceptance criteria for RF heating, magnetic induced torque, and magnetically induced displacement force and demonstrate that the device is safe for use in the MR environment. Image artifact was observed, but these artifacts were localized. Information regarding location and size of the artifacts has been included in the Instructions for Use. Biocompatibility testing was also completed for patient contacting materials.

CIVCO also prepared a white paper on data collected by the University Hospital Zurich in Switzerland on the trUpoint ARCH™ device. This paper documented, based on Zurich's data, that the device immobilizes patients within 1 mm during treatment (intrafraction). This paper also documented, based on Zurich's data, that when comparing CT simulation images to daily image matching, the trUpoint ARCH device is equivalent to a competitor system with respect to interfraction patient shifts. This data is pending publication by the University Hospital Zurich.

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G. Conclusion

This premarket submission for the Head Immobilization System 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. Based on comparison against the predicate devices and MR safety testing, the Head Immobilization System is safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

MEDTEC, Inc. d/b/a CIVCO Medical Solutions
% Ms. Amanda Stahle
1401 8th Street S.E.
ORANGE CITY IA 51041

March 4, 2014

Re: K132908

Trade/Device Name: Trupoint Arch, Nasion Cushion, Bite Cup, Trupoint Arch Storage
Plate, Trupoint Arch Base Lock Replacement Kit

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: II

Product Code: IYE

Dated: January 21, 2014

Received: January 24, 2014

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
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): K132908

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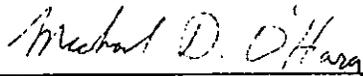
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)

Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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