K132084
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CIVCO MEDICAL SOLUTIONS

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Section 5 – 510(k) Summary

SEP 2 6 2013

A. Submitter Information

Submitter Name & Address:	MEDTEC, Inc. d/b/a CIVCO Medical Solutions 1401 8th Street SE Orange City, Iowa 51041
Contact Person:	Amanda Stahle, Regulatory Affairs Specialist Telephone: 319-248-6628, Fax: 877-218-0324 amanda.stahle@civco.com
Date Summary Prepared:	June 28, 2013
Trade Name:	Protura Couch Software 1.3.0
Common Name:	Treatment Couch Software
Classification Name:	Powered radiation therapy patient support assembly
Classification Number:	Class II under 21 CFR 892.5770
Review Panel:	Radiology
Product Code:	JAI

B. Predicate Device

MEDTEC, Inc. d/b/a CIVCO Medical Solutions claims the proposed device to be substantially equivalent to the following device:

510(k) Number	Device Name	Product Classification/ Code	Submitter Name
K122201	PROTURA COUCH SOFTWARE	892.5770/JAI	MED-TEC, Inc. D/B/A CIVCO MEDICAL SOLUTIONS

Both the proposed device and the predicate device are patient positioning software systems that interface with the Couch Hardware (K031866). Six degrees of freedom patient positioning corrections are sent from the Protura Couch Software to the Couch Hardware for implementation. Both the proposed device and the predicate device may interface with a record and verify system (Elekta MOSAIQ), Linac software (Elekta iCOM), Linac safeguard systems (Elekta touch guard and External Inhibit), and/or image guidance systems (Elekta XVI and VisionRT AlignRT). The proposed device adds interface capability with the following Varian systems: record and verify system (Varian ARIA), Linac software system (Varian 4DTC), Linac safeguard system (Varian 4DTC beam authorization), and image guidance system (Varian OBI). The proposed device also includes bug fixes and other functionality improvements. Testing has demonstrated that the proposed device is substantially equivalent

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to the predicate device in regards to safety, effectiveness, and performance, and the additional interfaces provided by the proposed device did not diminish the safety or effectiveness of the device.

C. Device Description

The proposed device, the Protura Couch Software 1.3.0 (Part No. MT6XSM1.3.0), is patient positioning software used in radiation treatments in conjunction with an Image Guided Radiation Therapy (IGRT) system. The Protura Couch Software interfaces with the Couch Hardware (K031866) and is intended to position the patient after diagnostic decisions have been made based on results from an IGRT system. The Protura Couch Software allows the user to control patient positioning with six degrees of freedom from outside of the treatment room. The Protura Couch Software also includes the ability to interface with record and verify systems, Linac software systems, Linac safeguard systems, and/or image guidance systems.

D. Indications for Use/Intended Use

The Protura Couch Software is intended to interface between record and verify systems, linear accelerator (Linac) software systems, Linac safeguard systems, and/or image guidance systems and the Protura Couch. The Protura Couch Software is also capable of operating the Protura Couch (6 Degree Axis Couch).

E. Technological Characteristics

Both the proposed device and the predicate device are interface software systems that are intended to operate the Couch Hardware (K031866). Both the proposed device and the predicate device interface with a record and verify system, Linac software, Linac safeguard systems, and/or image guidance systems. The proposed device interfaces with an additional record and verify system, Linac software system, Linac safeguard system, and image guidance system. The proposed device and the predicate device are programmed in C#. The proposed device operates on Windows 7 (64 bit) whereas the predicate device operates on Windows XP SP3 (32 bit), Windows 7 (32 bit), and Windows 7 (64 bit).

F. Non-Clinical Performance Data

Non-clinical performance testing was conducted for the following characteristics:

- Movement of the Protura Couch
- Interfacing with External Systems
- Couch Pedestal and Isocenter Alignment
- Patient Record Handling

All testing confirmed that the Protura Couch Software 1.3.0 is safe and effective for its intended use.

G. Clinical Performance Data

No clinical testing was performed in the evaluation of this medical device.

H. Non-Clinical Performance Data Conclusions

The conclusions drawn from the tests are that the Protura Couch Software 1.3.0 is substantially equivalent to the predicate device in regards to safety, effectiveness, and performance, and the additional interfaces have not diminished the safety or effectiveness of the device.

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

September 26, 2013

MED-TEC, Inc. d/b/a CIVCO Medical Solutions
% Ms. Amanda Stahle
Regulatory Affairs Specialist
1401 8th Street SE
ORANGE CITY IA 51041

Re: K132084
Trade/Device Name: Protura Couch Software 1.3.0
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: JAI
Dated: July 3, 2013
Received: July 5, 2013

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,

Michael D. O'Hara 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): K132084

Device Name: Protura Couch Software 1.3.0

Indications for Use: The Protura Couch Software is intended to interface between record and verify systems, linear accelerator (Linac) software systems, Linac safeguard systems, and/or image guidance systems and the Protura Couch. The Protura Couch Software is also capable of operating the Protura Couch (6 Degree Axis Couch).

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132084