



K122201

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AUG 30 2012

Section 5 – 510(k) Summary

A. Submitter Information

Submitter Name & Address: MED-TEC, 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
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Date Summary Prepared: July 10, 2012

Trade Name: Protura Couch Software
Common Name: Treatment Couch Software
Classification Name: Powered radiation therapy patient support assembly
Classification Number: 892.5770
Product Code: JAI

B. Predicate Device

MED-TEC, 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
K034054	PRO SERIES COUCH SOFTWARE, MODEL MT-PRO100	892.5770/JAI	MED-TEC, Inc.

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 software to the Couch Hardware for implementation. The predicate device also interfaces with a treatment planning system whereas the proposed device interfaces with a record and verify system, linear accelerator (Linac) software, Linac safeguard systems, and/or image guidance systems. Testing has demonstrated that the proposed device is substantially equivalent 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.

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Coralville Office	2301 Jones Blvd.	Coralville, IA 52241	USA	P 319.248.6757	F 319.248.6660
Europe Office	Pasteurstraat 6	2811 DX Reeuwijk	The Netherlands	P +31(0) 182.394495	F +31(0) 182.395014
Orange City Office	1401 8th Street SE	Orange City, IA 51041	USA	P 712.737.8688	F 712.737.8654



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C. Device Description

The proposed device, the Protura Couch Software (MT6XSMEU), 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 Protura 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 a record and verify system, Linac software, Linac safeguard systems, and/or image guidance systems.

D. Indications for Use/Intended Use

The Protura Couch Software is intended to interface between a record and verify system, linear accelerator (Linac) software, 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 Protura Couch Software and the predicate device are interface software systems that are intended to operate the Couch Hardware (K031866). The predicate device interfaces with a treatment planning system whereas the Protura Couch Software interfaces with a record and verify system, Linac software, Linac safeguard systems, and/or image guidance systems. The Protura Couch Software is programmed in C#, the predicate device is programmed in C, C#, C++, and Java. The Protura Couch Software runs on Windows XP SP3 (32 bit), Windows 7 (32 bit), and Windows 7 (64 bit); the predicate runs on Windows 2000.

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 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 and Clinical Performance Data Conclusions

The conclusions drawn from the tests are that the Protura Couch Software 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

AUG 30 2012

Re: K122201

Trade/Device Name: Protura Couch Software
Regulation Number: 21 CFR 892.5770
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: JAI
Dated: July 17, 2012
Received: July 25, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

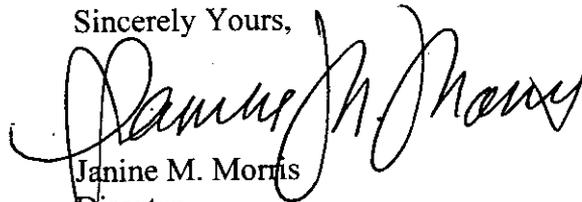
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Protura Couch Software

Indications for Use: The Protura Couch Software is intended to interface between a record and verify system, linear accelerator (Linac) software, 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
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122201