

510(K) SUMMARY
(as required by 807.92(c))

MAY 14 2010

Submitter of 510(k): MEDTEC, Inc.
1401 8th Street SE
Orange City, IA 51041-0320
USA

Phone: 712-737-8688
Fax: 712-737-8654

Contact Person: Jenny Jones

Date of Summary: January 15, 2010

Trade/Proprietary Name: MRI Patient Positioning Devices

Classification Name: MRI Patient Positioning Devices

Product Code: LNH CFR 892.1000

Intended Use:

Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.

Device Description:

The CIVCO Patient Support Devices have been used for many years and were previously cleared under 510(k)'s. This 510(k) is to have these identical Class II products cleared for use in an MRI environment.

Predicate Devices:

Hip and Pelvic Immobilization System: Pelvic Thermoplastics, Pelvic Vac-Lok, Pelvic Board

- K950866 – MEDTEC Inc, Hip Fix, Hip and Pelvic Fixation
- K080072 – CIVCO Medical Solutions, MRI Patient Positioning Devices

Breast and Thorax Immobilization System: Belly Board, Arm Positioner

- K060737 – SINMED Positioning Devices
- K080072 – CIVCO Medical Solutions, MRI Patient Positioning Devices

Lower Extremity Immobilization System: Knee Positioner, Foot Positioner

- K060737 – SINMED Positioning Devices
- K973842 - MEDTEC Inc, Carbon Fiber Conformal Couch Top
- K080072 – CIVCO Medical Solutions, MRI Patient Positioning Devices

Head and Neck Immobilization System: Baseplates, Head Immobilization
Thermoplastics, Headrests, Head Extension

- K060737 – SINMED Positioning Devices
- K080072 – CIVCO Medical Solutions, MRI Patient Positioning Devices

General Support System: General Support Cushions

- K060737 – SINMED Positioning Devices
- K080072 – CIVCO Medical Solutions, MRI Patient Positioning Devices



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

MedTec, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technologies Services LLC
1394 25th Street NW
BUFFALO MN 55313

MAY 14 2010

Re: K093738
Trade/Device Name: MRI Patient Positioning Devices
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 28, 2010
Received: April 29, 2010

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. 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.

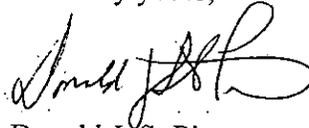
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Donald J. St. Pierre
Acting 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): K093738

Device Name: MRI Patient Positioning Devices

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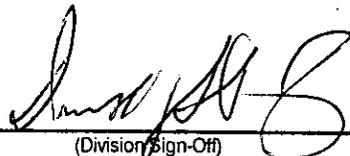
Prescription Use X
(Part 21 CFR 801 Subpart D)

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 Diagnostic Devices (OIVD)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093783

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