K111340
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JUN 28 2011

510(k) SUMMARY OF SAFETY & EFFECTIVENESS
(As required by 21 CFR 807.92)

CIVCO MR & Radiological Patient Positioning Devices

A. General Information

Submitter's Name: MEDTEC, Inc. dba CIVCO Medical Solutions
Address: 1401 8th Street SE, Orange City, Iowa 51041
Telephone No.: phone (712) 737-8688 fax: (712) 737-8654
Contact Person: Ms. Jenny Jones, Senior Quality Engineer

Establishment Registration Number: 1937223
MEDTEC, Inc. dba CIVCO Medical Solutions is registered as a medical device manufacturer.

Device Trade: **MR & Radiological Patient Positioning Devices**
Device Common: MR & Radiological Patient Positioning Devices
Device Classification Name: MR & Radiological Patient Positioning Devices

Classification: Class II under 21 CFR 892.1000 & 892.5050
Classification Panel: MR & Radiology
Classification Procode: LNH & IYE

Performance Standards: No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.

B. Device Description

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

Various sizes and shapes of patient positioning devices are offered in order to install on a specific system which the device is used on and/or the body region to be positioned.

Devices are sold non-sterile and may be re-used for multiple patient or single patient use if set-up for a single patient.

C. Indications for Use/Intended Use

CIVCO Patient Positioning Devices are used to aid in the support and positioning of patients during MR, radiological, and other procedures.

D. Predicate Device(s)

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

Identification of legally marketed device to which MEDTEC, Inc., doing business as *CIVCO Medical Solutions,* is claiming equivalence:

- **Head and Neck Immobilization System**
  - Kevlar Head and Shoulder Baseplate (Type-S Overlay)
    - 20CFHNSUB2 MR Kevlar Type-S Overlay

- **Body Immobilization System**
  - Body Immobilization Rails-Only System (Rails and Lok-Bars)
    - MTSBRT051 Rails-Only System 53cm Prodigy
    - MTSBRT050 Rails-Only System 53cm Interloc
    - MTSBRT056 Rails-Only System 53cm Exact
    - MTSBRT053 Rails-Only System 50cm Prodigy
    - MTSBRT052 Rails-Only System 50cm Interloc
    - MTSBRT057 Rails-Only System 50cm Exact
    - MTSBRT055 Rails-Only Lok-Bar
  - Body Immobilization Bridges (Body Pro-Lok Bridges)
    - MTSBRT039 Body Pro-Lok Bridge (Type1B)
    - MTSBRT007 Body Pro-Lok Bridge (Type 2)
    - MTSBRT031 Body Pro-Lok Bridge (Type 3)
  - Body Immobilization Respiratory Plate
    - MTSBRT003 Respiratory Plate
  - Body Immobilization Forehead Brace
    - MTSBRT018 Forehead Brace
  - Body Immobilization Patient Hand Grips
    - MTSBRT005 Patient Hand Grips
    - MTSBRT0051 Patient Hand Grips (Mirror)
  - Body Immobilization Clam-Lok Cushion
    - MTSBRT202 Clam-Lok Cushion
  - Body Immobilization Shoulder Bridges
    - MTSBRT038 Shoulder Bridge 2

E. Substantial Equivalence Summary

MEDTEC, Inc., doing business as *CIVCO Medical Solutions,* claim the proposed devices to be substantially equivalent to the devices previously cleared by FDA in the following 510k's: K972842, K080072, K093738, K935000 and K954225. MEDTEC, Inc., doing business as *CIVCO Medical Solutions,* claim this equivalence because the proposed devices have equivalent intended uses, manufacturing, quality systems, device body contacting category and safety parameters.

Parameter	MR & Radiological Patient Positioning Devices	Predicate Device Patient Positioning Devices
Intended Use / Indications for Use	CIVCO Patient Positioning Devices are used to aid in the support and positioning of patients during MR, radiological, and other procedures	CIVCO Patient Positioning Devices are used to aid in the support and positioning of patients during radiological and other procedures
Manufacturing	Same.	Machined, injection molded, formed, assembled, painted
Quality Systems	Same.	▪ FDA/QSR cGMP 21CFR Part 820. ▪ ISO 9001 / ISO 13485
Device Body Contact Category	Same.	Surface devices, intact skin; limited contact duration (< 24 hours)
Safety	Same.	Testing is in accordance with -ISO 10993-Part 1 Biological Evaluation of Medical Devices, FDA Blue Book Memorandum #G95-1, and FDA-Good Laboratory Practices (GLP).

Characteristics which have changed between the proposed and predicate devices include changes in the design and materials which have now been tested for use in an MR environment to ensure these differences have no effect on safety and effectiveness of the device. These products have been tested to demonstrate that they can be safely used in both radiological and in MR environments and biocompatibility for patient contacting materials. The product labeling, including brochures has been updated to include MR safe or MR conditional labeling with applicable MR environments. All products in this submission are non-metallic and marked as MR safe with exception of the Clam-Lok Cushion which is a size variation of a previously cleared device (Vac-Lok Cushion (K080072 and K093738) for use in MR environments with a MR conditional labeling.

Attached in section 4 are Substantial Equivalence Summary checklists which represent an evaluation made to determine whether the characteristic differences from the predicate device requires the submission of a new 510k. Changes have been identified in this evaluation of the subject devices as compared to the predicate device. Changes in regards to labeling, design, performance, and material have been determined to not have the potential to affect the safety and effectiveness of the device.

F. Conclusions

This premarket submission for CIVCO MR & Radiological Patient Positioning Devices 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 current product offering and predicate devices, CIVCO MR & Radiological Patient Positioning Devices are safe and effective for their intended and indicated use.

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. Jenny Jones
Senior Quality Engineer
MEDTEC, Inc., doing business as CIVCO Medical Solutions
1401 8th Street SE
ORANGE CITY IA 51041

JUN 28 2011

Re: K111340
Trade/Device Name: MR Patient Positioning Devices
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and IYE
Dated: May 10, 2011
Received: May 12, 2011

Dear Ms. Jones:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
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): TBD

Device Name: MR Patient Positioning Devices

Indications For Use:

CIVCO Patient Positioning Devices are used to aid in the support and positioning of patients during MR, radiological, and other procedures.

Prescription Use __X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

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

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