K102236.

HOVERTECH International

"510(k) SUMMARY" as required by section 807.92(c)

Submitter Information:

D.T. Davis Enterprises, LTD
T/A HoverTech International
513 S. Clewell Street
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NOV 19 2010

Contact Person:

Susan Pavelko
Quality Manager
D. T. Davis Enterprises, LTD

Date Summary Prepared: March 17, 2010

Trade Name: HoverTech International® Transformer

Common Name: Stretcher, Wheeled, Powered

Classification Name: Powered wheeled stretcher (21CFR 890.3690, Product Code INK)

Legally Marketed Device: Transmotion Medical Model TMM6 Power Drive Chair

Device Description: The HoverTech International Transformer is a battery powered patient transport device with a motorized drive to aid the caregiver in maneuvering the device while transporting patients within care facilities. Its intended function and use is to transport patients to various areas within the patient care facility and may contain supports for fluid infusion equipment. It can also be used to support the patient in a seated or supine position during examinations, physical therapy and other clinical activities within the patient care facility. The adjustability of the Transformer allows for better patient access by caregivers and also provides for enhanced patient comfort.

Intended use: This device is a motorized device intended for medical purposes to assist in the transport of patients to and from the bath, beds, chairs, treatment modalities, and transport vehicles. The FDA has classified the device as a Class II device.

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Device Comparison: The HoverTech International® Transformer is substantially equivalent to the Transmotion Medical Model TMM6 Power Drive Chair in function and intended use. Any minor differences described in the submission between the HoverTech International® Transformer and that of the predicate devices does not raise any new issues of safety or effectiveness. The intended use, basic technology, and performance characteristics of the system are the same.

The subject device is intended to be used in any clinical environment where patient care is administered. Health facilities ordinarily used stretchers for patient treatment, recovery and for transportation to and from treatment modalities, i.e. physical therapy, diagnostic radiology, etc.

The labels and labeling (Operator's and Maintenance Manuals) provide information for the safe operation by the caregiver/user and the intended operation features.

No performance standards or special controls have been promulgated for powered patient transport devices under sections 513 and 514 of the FD&C Act.

Safety Testing and performance characteristics have been conducted and successfully completed in order to ensure compliance with specifications. These reports are maintained as required by 21 CFR 820, Quality Systems Regulations.

An assessment of known and reasonable hazards has been conducted to ensure that any risk associated with the device as of the date of product release is as low as reasonably possible. Design review has been conducted by a cross-functional team, including but not limited to regulatory, quality, engineering and manufacturing.

The device will comply with the following voluntary standards:

- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988 (General), Amendment 1, 1991-11, Amendment 2, 1995-03

- IEC 60601-1-2. (First Edition, 1993-04), Medical Equipment –Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests (General)

- IEC 60601-2-38 Issue: 1996/10/01 Ed: 1 Medical Electrical Equipment – Part 2-38: Particular Requirements for the Safety of Electrically Operated Hospital Beds; Amd. 1: 12-1999- Applicable parts only (loading and pinch points)

- UL 2601-1 (2nd Edition) Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety – Issued: 2003/04/24 Edition 1, Revision: 2006/04/26

- CAN/CSA C22.2 No. 601.1-M90 Standard for Medical Equipment

- ISO 10993-5: 1999, Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)

- ISO 10933-10: 2002, Biological evaluation of medical devices- Part 10: Tests for irritation and Sensitization pp. 6 – 10, 21 (Biocompatibility)

- ISO 10933-10: 2002, Biological evaluation of medical devices- Part 10: Tests for irritation and delayed type hypersensitivity pp. 18-20. (Biocompatibility)

The Transformer and predicate powered patient transport included in this submission are substantially equivalent.

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

D.T. Davis Enterprises, LTD
% HoverTech International
Ms. Susan Pavelko
Quality Manager
513 South Clewell Street
Bethlehem, Pennsylvania 18015

NOV 19 2010

Re: K102236
Trade/Device Name: The HoverTech International HoverTrans™ Transformer
Regulation Number: 21 CFR 890.3690
Regulation Name: Powered wheeled stretcher
Regulatory Class: Class II
Product Code: INK
Dated: August 5, 2010
Received: August 25, 2010

Dear Ms. Pavelko:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Mark D. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102236.

Section 4:

Indications for Use

NOV 18 2010

510(k) Number (if known):

Device Name: The HoverTech International HoverTrans™ Transformer

Indications For Use: The device is a motorized device intended for medical purposes to assist in transfer of a patient to and from beds, chairs, treatment facilities, wheelchairs or transport vehicles.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102236