K992545

510(k) Summary

TM-300 Traction System

Common/Classification Name: Powered Traction Unit, 21 CFR 890.5900

Ito Co., Ltd.
3-3-3 Toyotama-Minami
Nerima-ku, Tokyo 176-8605
JAPAN

Contact: H. Okada , Prepared: July 29, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The **TM-300 Traction System** is a powered traction unit, a device classified by the regulation 21 CFR 890.5900 as a Class II device. The **TM-300 Traction System** is substantially equivalent to the DRS System manufactured by Professional Distribution Systems, Inc., which was cleared on June 24, 1998 as K981822.

B. DEVICE DESCRIPTION

The **TM-300 Traction System** is an automatic intermittent traction system for traction therapy. The patient always holds a safety switch that can interrupt treatment if it becomes uncomfortable. Several "mechanical waveforms" are available for selection by the operator, including:

(1) Basic intermittent traction
(2) Incremental intermittent traction
(3) Incremental and decremental intermittent traction
(4) Residual intermittent traction
(5) Incremental and residual intermittent traction
(6) Incremental, decremental and residual intermittent traction
(7) Basic continuous traction
(8) Incremental continuous traction

The residual tractive force, the duration time setting, the pause time setting, the tow speed, and the treatment time setting are all programmable up to specified limits. For forces selected above 18 kg, the system always asks for confirmation of the selected value by the operator before proceeding. A limit switch prohibits output exceeding 100 kg.

C. INTENDED USE

The TM-300 Traction System is indicated for relief of pain in cases of low back pain. Each treatment consists of a physician-prescribed session designed to provide static, intermittent, or cycling distraction forces to relieve pressure on structures that may be causing low back pain. The TM-300 relieves pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. These indications are identical to those cleared for the predicate device.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **TM-300 Traction System** is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices. The **TM-300 Traction System** has the same technological characteristics as the predicate devices. This premarket notification has described the characteristics of the **TM-300 Traction System** in sufficient detail to assure substantial equivalence except for a few of the characteristics where performance testing was carried out (e.g., electrical safety).

E. TECHNOLOGICAL CHARACTERISTICS

The TM-300 and the predicate device are line-powered traction devices. The TM-300 and the predicate device are microprocessor-based and employ digital and analog circuits to produce the specified waveforms and traction levels. Both employ an LCD screen as the user interface.

F. TESTING

Testing was carried out to assure compliance with recognized electrical safety standards. Ito was issued a certificate of compliance with the EN-60601 standard for electrical safety by TUV.

TUV has issued an Attestation of Conformity for the TM-300 in regard to the EN 60601-1-2 standard for electromagnetic compatibility.

The design qualification testing demonstrated that the TM-300 met its design specifications.

G. CONCLUSION

This pre-market submission 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 1999

T. Whit Athey, Ph.D.
Senior Consultant
Ito Co., Ltd.
C/O C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K992545
Trade Name: TM-300 Traction System
Regulatory Class: II
Product Code: HST
Dated: July 30, 1999
Received: July 30, 1999

Dear Dr. Athey:

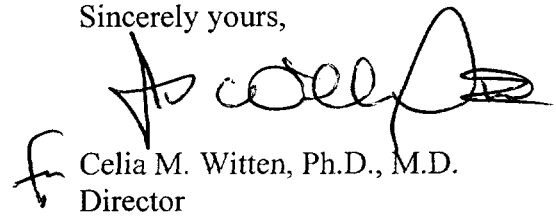
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K992545

Device Name: TM-300 Traction System

Indications For Use:

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(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 General Restorative Devices
510(k) Number K992545

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)