510(k) Summary as Required by 21 CFR 807.92

OCT 26 2012

Submitter: MT Tables, LLC
15 W. Mill Street
Aurora, MO 65605

Contact Person: Milburn Tennis
(417) 678 2880

Date Prepared: 01-02-2012

RE: K111588

Device Trade Name: Legacy-500 Massage Table

Common Name: Massage Table, IST, Roller Table
21 CFR 890.5880

Regulatory Class: Class II

Product Code: JFB

Part 890- : SEC. 890.5880 Multi-Function Physical Therapy Table

Substantial Equivalence: K010252 Magnum, K002390 Quantum 400, K993461 Quest IST

Device Description: Legacy-500 Massage Table is an electrically powered, motorized, multifunctional physical therapy table. The intended use is to provide muscle relaxation therapy by delivering a soothing massage. It is designed to travel throughout the back area in a smooth transition but can also stop in one specific area. Pressure of the massage can be adjusted from one (lowest setting) to six (highest setting) and is displayed by six lights. Rollers can massage clockwise or counter-clockwise and the indicator displays the position on the back. The timer allows the table to run from one to thirty minutes shutting power off after treatment time and returning the pressure of the rollers to the lowest setting, at any time during treatment the timer can be manually shut off to stop the table by user or patient. The only patient contacting component is the table top that the patient lays on covered in vinyl upholstery.

Intended Use: Legacy-500 Massage Table is designed to release muscle tension and deliver a soothing massage.

Technological Aspects: A comparison of the device features, intended use and other Information demonstrate that the Legacy-500 Massage Table Is substantially equivalent to the cleared for commercial distribution per K010252, K002390 and K993461.

Comparison	Legacy-500	K010252	K002390	K993461
Intended use: Designed to release muscle tension and deliver a soothing massage.	Yes	Yes	Yes	Yes
Substantially same size and shape.	Yes	Yes	Yes	Yes
Achieve the same physiogical effects	Yes	Yes	Yes	Yes
Three six inch diameter massage rollers	Yes	Yes	Yes	Yes
Clockwise and counter-clockwise roller rotation	Yes	Yes	Yes	Yes
Adjustable roller pressure to place varying degree of pressure on muscles on back	Yes	Yes	Yes	Yes
Height of rollers can adjust three inches above baseline table surface	Yes	Yes	Yes	Yes

Comparison	Legacy-500	K010252	K002390	K993461
30 minute timer that shuts power off after cycle time and is also used as the safety shut off	Yes	Yes	Yes	Yes
Have the same type of frame construction	Yes	Yes	Yes	Yes
Have steel roller carriage	Yes	Yes	Yes	Yes
Can massage full back or selectable area	Yes	Yes	Yes	Yes
Have lighted height indicator	Yes	Yes	Yes	Yes
Have same style electrical components and motors	Yes	Yes	Yes	Yes
Ten (10) minute recommended treatment time	Yes	Yes	Yes	Yes
Covered in vinyl upholstery	Yes	Yes	Yes	Yes
One control / indicator panel at head end of table to prevent patient from kicking controls when getting on or off table	Yes	No	No	No
Indicator panel at head end and control panel at foot end of table	No	Yes	Yes	Yes
Has optional hand held control and heat option	No	No	Yes	No

A comparison of the device features, intended use and other information demonstrates that the Legacy-500 is substantially equivalent to the cleared for commercial distribution per K010252, K002390 and K993461.

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

MT TABLES, LLC
% Mr. Milburn Tennis
Owner
15 West Mill Street
Aurora, Missouri 65605

OCT 26 2012

Re: K111588
Trade/Device Name: Legacy-500
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table
Regulatory Class: Class II
Product Code: JFB
Dated: October 09, 2012
Received: October 09, 2012

Dear Mr. Tennis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K111588

Device Name: Legacy-500

Indications For Use: The intended use is to provide muscle relaxation therapy by delivering a soothing massage.

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)

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

510(k) Number K111588