FEB - 6 1998 K974626

Attachment 510(k) Summary
for
Goodman's P.T. Machine

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: December 10, 1997

Name of Device

P.T. Machine

Common or Usual Name

Physical therapy table; Chiropractic table

Classification Name

Multi-functional physical therapy table

Predicate Devices

(1) Williams Healthcare Systems Inc.'s Combi MTS 1.5
(2) Hill Laboratory Company's Stationary Top Anatomotor.

Intended Use

The P.T. Machine and the predicate multi-functional physical therapy tables have the same intended use. The tables are intended to be used to provide paraspinal treatment in the form of articulation pressure, heat, or vibration.

Principles of Operation

The P.T. Machine and the predicate devices have very similar principles of operation. First, the Chiropractor determines an appropriate treatment plan with respect to articulation pressure, heat, or vibration. Second, the clothed patient lays in the supine position on the table. Third, the patient or Chiropractor programs the table to deliver the proper pressure, heat, and vibration. Fourth, the table delivers the treatment according to the Chiropractor's specifications. Fifth, the treatment ends after the designated duration.

Technological Characteristics

The P.T. Machine and the predicate devices have very similar technological characteristics. Both the P.T. Machine and the predicate devices are AC-powered physical therapy tables that consist of rollers to provide articulation pressure, a heat source to provide heat therapy, and a vibrational source to provide massage therapy. Moreover, all three devices are programmable devices that may be programmed either by the Chiropractor or the patient. There are only five minor technological differences among the P.T. Machine and the predicate devices:
(1) the dimensions of the tables; (2) the design of the rollers that exert articulation pressure on the spine; (3) the range of the programmable variables and the constant parameters; and (4) the manner in which the variables are programmed. None of these differences raise any new questions of safety or effectiveness because: (1) the P.T. Machine can accommodate most patients; (2) the P.T. Machine provides a constant articulation pressure that is within the range of the articulation pressures of the predicate devices; (3) the range of the P.T. Machine's programmable variables and constant parameters are within the ranges of the predicate devices' programmable variables and constant parameters; and
(4) the P.T. Machine's use of a magnetic card and card reader reduces the possibility of patient error in inputting data and other legally marketed devices use this technology for similar purposes.

Summary Basis for Finding Substantial Equivalence

The P.T. Machine and the predicate devices have the same intended use and very similar principles of operation and technological characteristics. The minor differences among the devices do not raise any new questions of safety or effectiveness. Therefore, the P.T. Machine is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 1998

Mr. Marc H. Bozeman
Hogan & Hartson L.L.P.
Representing Goodman, Goodman & Goodman
500 South Grand Avenue, Suite 1900
Biltmore Tower
Los Angeles, California 90071

Re: K974626
P.T. Machine
Regulatory Class: II
Product Code: JFB
Dated: December 10, 1997
Received: December 11, 1997

Dear Mr. Bozeman:

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 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 (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,

for 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

510(k) Number (if known):_____

Device Name: P.T. Machine

Indications For Use:

To provide paraspinal treatment in the form of articulation pressure, heat, and vibration.

(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 K94626

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)