MAY 11 1998 K980021

DR. DAVID F. CUCCIA, D.C.
ADVANCED BACK TECHNOLOGIES
227 Jackson Ave.
Syosset, NY 11791
Phone: 516-544-4511 Fax: 516-364-1998

"510 (k) SUMMARY"

Applicant's Name: **David F. Cuccia, D.C.**
227 Jackson Ave.
Syosset, NY 11791
Contact Person: **David F. Cuccia, D.C.**
Phone: **516-364-1717**
Fax: **516-364-1998**

The legally marketed device or predicate, to which I am claiming substantial equivalence :
AUTO-TRAC TABLE
510(k) NUMBER K844233
Device/Trade Name : **EXTENTRAC**
Common Name : **Physical Therapy Table, Multipurpose**
Classification Name : **Multipurpose Physical Therapy Table**
Classification (C.F.R. Section): **Class II Device (Section 890.5880)**
Product Code : **89JFB**
Panel : **Orthopedic Panel**
Model Number : **DC 3**
Date Summary Prepared: **December 30, 1997**

INTENDED USE

EXTENTRAC'S INTENDED USE IS TRACTION.

EXTENTRAC, has the same intended medical use, **"traction"**, as its comparable predicate device (Auto-Trac) by Chattanooga Corp., where reference to its intended use was elucidated on page 122, and 123, of Dr. Natchev's book entitled "A Manual On Auto-Traction Treatment For Low Back Pain". This book was supplied to the FDA as part of its 510(K) submission. (Please refer to Chattanooga's letter dated October 9, 1984). A copy of both pages, containing it's intended use, is included with this submission. Please see Section 6, Page(s) 6-1, and 6-2.

*Extentrac's and Auto-Trac's principle intended use is traction, through active pulling by the patients own power called active traction, or total passive traction using "gravity". However, both devices by similar design characteristics, enable a patient to activate table control biofeedback, and/or patient relaxation without necessarily requiring traction. This was elucidated on page 122 , of Dr. Natchev's book entitled "A Manual On Auto-Traction Treatment For Low Back Pain", as referred to above.

DESCRIPTION OF DEVICE

Extentrac falls under the classification of a multipurpose physical therapy table whose components are constructed of welded, bolted, tubular (solid and hollow), or flat plate heavy gauge steel and high strength aluminum), plywood, vinyl, hydraulic cylinders, pump, motor, wires, solenoid valves, relays, and switches.

EXTENTRAC has **two** major sections connected to each other through a pivot shaft arrangement:

1. A rectangular base platform (Bottom Section): - Its function is to support and provide the pivot means for the rotating top section. Extentrac's stationary patient foot platform, is integral with this base platform, and therefore does not rotate with the patient. It also provides the telescoping means enabling elevation of the top patient platform section (rotating/tilting assembly), to effect height accommodations and different treatment protocols. Please refer to Section 2, Page 2-16.

2. Rotating/tilting patient platform (Top Section): - It consists of three individual, separated patient support cushions, mounted to a metal support sub-frame, through a pivot connection with the top end of the weighted base platform. The patient support sub-frame (immediately below patient cushions) has the upper $2/3^{rds}$. of its length angled in a backwards direction, and at 30 degrees in relation to its lower $1/3^{rd}$. This arrangement allows the upper torso support cushion to move downward 30 degrees. Extentrac's patient platform is designed to rotate about this pivot point . Please refer to Section 2, Page 2-16.

FUNCTIONAL ELEMENTS

- **Underarm/shoulder supports with integral hand grips**. This is the preferred arrangement for safe patient support. This comfortably supports the patient's upper torso while preventing outward and downward movement of the patient. The hand grips are an integral part of the upper arm supports, providing secure attachment of patient to the patient platform during treatment, and are the places of attachment of the emergency table stop switch. They are also the location of the auxiliary patient table rotation and lumbar support switches. These underarm and shoulder supports are to be used in combination with either the abdominal strapping (Extentrac's "seat belt"), or the universal thoracic harness. They provide increased safe patient positioning as compared to the Auto-Trac device method of patient securing. Please see Section 6, page 6-4, in which the patient must rely **only** on strapping methods. With the use of these new underarm/shoulder supports, a metal support "cage" has essentially been added, physically preventing patient outward and downward movement. Please refer to Section 2-page 2-16, Letter(s) A.

- **Upper torso (thoracic) support cushion.** Manually moved, i.e. by pivoting at its bottom support, its top section locks into a desired position. Adjustable in a backwards direction up to 30 degrees. Upper torso support is capable of locking into any of these variable degrees. Please see Section 2- page 2-16, Letter B.

- **Lumbar back support pad (convex shaped).** Adjustable (extends or re-tracts) by either keypad activation or auxiliary patient activated. Provides increased ergonomic support, and varying degrees of extension of the lower back. Please refer to the section entitled : Scientific Concepts of Device: Please see Section 2- page 2-16, Letter C.

- **Separate calf/ankle support.** Adjustable manually up or down vertically , to accommodate different anatomical relationships. Adjustable through keypad switch, outward, away from table's plane, or back in the same plane as vertical table frame. Provides ability to retain patient's upper torso in the same plane as lower limbs or torso. Please see Section 2- page 2-16, Letter D.

- **Table Lift Functional Unit.** Contained in the rectangular base platform. Allows entire patient platform with **all** functional elements to be raised or lowered. Please refer to Section 2- page 2-16, Letter E., and Section 6- page 6-6, Letter E.

- **Overhead transverse horizontal gripping bar.** Please see Section 2, page 2-16, Letter F.

- **Protractor devices.** (Digital or analogue, which measures patient support frame degree of rotation.) Please refer to Section 2- Page 2-16, Letter G.

- **Hydraulic cylinder Table movement.** All Electric and software, hydraulic pump and motor, solenoid valves , are housed in protective sheet metal electrical box. (UL Listed) Please refer to Section 2- Page 2-16, Letter H.

- **Side platform railings located on Horizontal weighted base.** Please refer to Section 2- Page 2-16, Letter I.

- **Head support cushions/rolls in various sizes.** Please refer to Section 2- Page 2-16, Letter J.

ANTICIPATED FUTURE DESIGN ADDITIONS/ CHANGES :

1- **Ankle/foot strapping means.** Provides increased traction effect in the "active patient " protocol procedure in which the patient uses their arms to "self" pull against additional resistance provided by ankle strapping. Selective attachments to either both the weighted foot bottom platform base and/or the ankle and calf support element.
2- **Ankle/foot Weights.** Provides increased traction effect.
3- **Thomson AccuGlide T Series Linear Ball Guides** to substitute for Arm and Shoulder support roller means used for Arm and Shoulder support Translational movement, i.e. arm height movement.

TABLE ACTIVATION/CONTROL

PRACTITIONER CONTROLLED , HAND HELD KEYPAD WITH FUNCTION CONTROL SWITCHES PROVIDE MOVEMENT OF TABLE ELEMENTS

- (Main keypad location) Please refer to Section 6- Page 6-6, Letter K.

1. INDIVIDUAL KEYPAD FUNCTION CONTROL SWITCHES.

(Main keypad location)

DESCRIPTION OF SWITCHES

1- Lift - table/patient platform raises vertically and descends downward.
2- Rotation button - table/patient platform rotates backwards, and forwards.
3- Arm rotate up - safety arm pieces rotate up or down.
4- Arm vertical translation - safety arm supports move up or down along long axis of patient platform.
5- Lumbar support - Lumbar support extends outward, or re-tracts.
6- Leg/calf support - Leg /calf cushion moves outward or inward. Allows planar arrangement of entire patient platform.

2.- COMBINED FUNCTION SWITCHES

(Main keypad location)

Extentrac also has two keypad control switches which simultaneously combine two individual table functions. (Main keypad location)

DESCRIPTION OF SWITCHES

1- **LIFT AND ROTATE SWITCH** - *A separate key pad combination function button.* Patient platform raises in height, creating an increase in height of vertical platform. (a gain in vertical height) simultaneously in combination with patient platform backwards rotation. Calf/leg pad does not accompany rotation. Has reverse function.
2- **ROTATION AND LEG/CALF SWITCH** - *A separate keypad combination function button.* Patient platform rotation in a backwards direction, simultaneously with leg/ calf support outward movement. (Maintains planar pad arrangement). Has reverse function.

BASIC TABLE OPERATION (HOW IT WORKS)

Extentrac has three individual patient platform sections which are variably positioned by the activation of selected hydraulic cylinders, through continuos depression of two pole "toggle" type switches making up the hand held practitioner control keypad. This turns the hydraulic pump motor on, which forces hydraulic fluid into the selected cylinders, which in turn causes table rotation or movement of any other table functional units movement. Hydraulic activated movement stops immediately, by release of a keypad control switch. Micro-switches and mechanical stops provide protection at extremes of table movement. When the keypad button labeled "Table Rotation" is depressed and held, the patients are moved from the vertical to the horizontal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 1998

Dr. David F. Cuccia
Advanced Back Technologies, Inc.
227 Jackson Avenue
Syosset, New York 11791

Re: K980021
Trade Name: EXTENTRAC
Regulatory Class: II
Product Code: JFB
Dated: March 14, 1998
Received: March 19, 1998

Dear Dr. Cuccia:

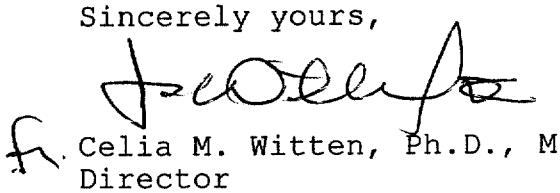
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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: Extentrac

INDICATIONS FOR USE:

-Replaces page 1-3 of 510(k) dated December 30, 1997

INDICATIONS FOR USE

Extentrac provides traction, for the relief of a variety of conditions involving anatomical dysfunctions of the lumbar spine including :

- localized low back pain
- peripheral radiation (radicular pain)
- protruding or herniated intervertebral discs.
- acute facet problems
- degenerative disc disease

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980021