K033126

Pg. 1 of 2

OCT 2 9 2003

Attachment #4

510(k) SUMMARY

Submitter's Name, Contact Person, Address, Phone, Fax, and Email

Behavioral Technology, Incorporated (BTI)
Susan E. Olsen
24 M Street
Salt Lake City, UT 84103
Phone: (801) 363-9017
Fax: (801) 363-9022
Email: susan@btimonarch.com

Device Name, Common/Generic Name and Classification Name

Proprietary Name:	MONARCH 21 Penile Plethysmograph
Common/Generic Name:	Penile Plethysmograph
Classification Name:	Monitor, Penile Tumescence

Predicate Device

Device Name:	CAT-600 Penile Plethysmograph, K936115

Description of the Device

MONARCH 21 Penile Plethysmograph consists of attached sensors, which measure penile tumescence. A laptop computer is used to store, tabulate, display and print out the acquired data.

Intended Use of the Device

The MONARCH 21's intended use is to measure sexual response to visual and auditory stimuli in male sexual offenders as an important part of evaluating individual treatment need and determining risk for recidivism.

Technological Summary between MONARCH 21 and its predicate device

MONARCH 21 provides all the functionality of it's predicate devices into a truly portable and easy-to-use system. Differences between MONARCH 21 and predicate devices were subjected to mechanical, electrical safety, software testing and clinical validation to demonstrate that they do not diminish safety and effectiveness. Intercom and auxiliary traces support technicians in making standardized assessments. Non-standardized assessment capability is available for research.

Non-Clinical Test Results

A precision machined aluminum calibration cone with graduated circumference sizes was used to measure the penile sensors full range of values. Secondary agents were tested using simulated equivalent values. All testing mimicked prior predicate device examination resulting in substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

Ms. Susan E. Olsen
Executive Vice President
Behavioral Technology, Inc.
24 M Street, Suite #1
SALT LAKE CITY UT 84103

Re: K033126
Trade/Device Name: MONARCH 21 Penile Plethysmograph System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LIL
Dated: September 26, 2003
Received: October 2, 2003

Dear Ms. Olsen:

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment #2

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

Applicant: Behavioral Technology, Incorporated

510(k) Number: K033126

Device Name: MONARCH 21 Penile Plethysmograph System

Indications for Use: The MONARCH 21 system's intended use is to measure sexual response to visual and auditory stimuli in male sexual offenders as an important part of evaluating individual treatment need and determining risk for recidivism.

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033126

Prescription Use ✓
(Per 21 CFR 801.109)