SEP 2 0 2001

K011964

Insight Millennium Plus

510(k) Summary

Submitted by:

Company Name:	Fasstech
Company Address #1:	155 Middlesex Turnpike
Company Address #2:	Burlington, MA 01803
Contact Person:	Lee Brody
Phone Number:	781.229.1500
Fax Number:	781.229.9035

Submitted on: June 22, 2001

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Section 1: Device Name

Common or Usual Name: Biofeedback Device
Proprietary Model Name: Insight Millennium Plus

Section 2: Indications for Use

- To measure bilateral differences in surface EMG along the spine
- To measure surface EMG along the spine during functional tasks
- To measure bilateral differences in skin temperature along the spine
- To measure Range of Motion of the three spinal regions
- To measure patient self-reported pressure sensitivity in joints and muscles
- To chart patient progress during the course of treatment

Section 3: Device Description

The Insight Millennium Plus is a non-invasive, multi-modality physiologic monitoring device. The Insight Millennium Plus contains the following four sensor types: (1) surface EMG used to measure muscle activity, (2) infrared temperature sensor used to measure skin temperature, (3) inclinometer used to measure end-point range of motion, and (4) algometer used to measure patient self-reported pressure sensitivity.

Hardware
The Insight Millennium Plus hardware consists of an instrument console and four different sensor types. All four sensor types plug directly into the front panel of the Insight Instrument Console. The Insight Millennium Plus Instrument Console is powered via a UL2601 listed wall mounted power supply. The Instrument Console is connected to a personal computer (IBM compatible) via an isolated serial port connection.

Software
The Insight Millennium Plus software displays real-time surface EMG, spinal Range of Motion, skin temperature and pressure readings, allowing the user to ensure that readings are stable prior to data collection. The Insight Millennium software allows the user to: (1) enter patient information, (2) record surface EMG, spinal Range of Motion, skin temperature and pressure readings, (3) graph surface EMG, spinal Range of Motion, skin temperature and pressure readings, and (4) print out reports.

Section 4: Predicate Device

This section documents the substantial equivalence of the Insight Millennium Plus to legally marketed devices. The Insight Millennium Plus is a modest expansion of the Insight Millennium. The Insight Millennium Plus expansion is limited to the addition of a fourth sensor type. The fourth sensor type is the Insight Algometer. The algometer is a calibrated pressure stimulus device. It measures pressure applied by examiner to elicit a response for pain tolerance, pain threshold, and trigger point tenderness. The Algometer utilized in the Insight Millennium Plus is substantially equivalent to the JTECH Commander™ Algometer (510(k): K971407):

Fasstech Insight Millennium (K990778)
JTECH Commander™ Algometer (K971407)

Feature	**Insight Millennium Plus**	Insight Millennium	Commander Algometer
Four Channels of surface EMG	**Yes**	Yes	N/A
Skin Temperature measurement via infrared thermal scanner	**Yes**	Yes	N/A
Range of Motion Sensor	**Yes**	Yes	N/A
Algometer	**Yes**	No	Yes
UL-2601 listed wall-mounted power supply	**Yes**	Yes	N/A
Opto-isolated RS232 output	**Yes**	Yes	N/A
A/D Converter	**12 bit, 8 channel**	12 bit, 8 channel	N/A
Algometer Skin Contact Area	**1.0 cm^2**	N/A	0.5 cm^2 or 1.0 cm^2
Instrument Body Material	**Machined Aluminum**	N/A	Machined Aluminum
Instrument Body Coating	**Powder Coated**	N/A	Powder Coated
Downloadable to PC	**Yes**	N/A	Yes
Range	**0-100 lbs**	N/A	0-100 lbs
Accuracy	**+/- 3%**	N/A	Not Published
Skin Contact Material	**ABS Plastic**	N/A	Not Published
Stand-alone capability	**No**	N/A	Yes

Section 5: Performance Specification

EMG

Electrodes:	4 ea. Smart Sensors with low-noise preamplifiers integral to electrode assemblies
Calibrated Range:	0.1 – 999 uV
Input Bias Current:	Less than 2.0 Picoamperes
Differential Input Impedance:	Greater than 1,000,000 Megaohms
Common Mode Rejection:	150 dB
Bandwidth:	20-500 Hz (50/60 Hz notch)
Noise:	Less than 0.1 uV (inputs shorted)
Detector:	Log power detector, 250 mS averaging filter.
Controls:	None

Range of Motion

Range:	360 degrees
Accuracy:	+/- 1 degree nominal
Controls:	Enter and Skip Buttons
Physical:	Case Material: Impact resistant, flame retardant ABS. 3.4"H x 3.5"W x 1.25"D. Weight 6.5 oz.

Temperature

Calibrated Range:	55°F - 120°F
Accuracy:	$\pm$0.2°F nominal
Sensors:	Two thermopile, fixed 2.5" apart (center-to-center)
Controls:	Enter button
Physical:	Case Material: Impact-resistant, Aluminum with 0.5" ABS Plastic Outer Ring.
Size:	5.5"L x 3.5"W x 2.5"H. Weight 15 oz.

Algometer

Calibrated Range:	0-100 lbs.
Accuracy:	$\pm$3% nominal
Contact Area:	1.0 cm^2
Sensor:	One pressure transducer attached to a stiff rod.
Controls:	Enter button
Physical:	Case Material: Impact-resistant, Aluminum with 3.0" ABS Plastic Stiff Rod.
Size:	5.5"L x 1.75"W x 2.5"H. Weight 9 oz.

Instrument Console

Inputs:	4 each EMG electrodes 1 each inclinometer

	1 each temperature sensor 1 each algometer sensor
Output:	Opto-isolated RS232 (9 pin sub-D jack)
A/D converter:	12 bit, 8 channel
Controls:	None
Power:	12V, 500 mA UL-2601 listed wall-mounted power supply.
Physical:	Case Material: Impact resistant, flame retardant ABS. 3.5"H x 8.375"W x 9"D. Weight 3 lbs. 11 oz.

Section 6: Patient Safety

The Insight Millennium Plus patient safety is assured by the following design architecture:

Patient Isolation Circuitry: There are three primary components to the patient isolation circuitry: (a) an external plug-in medical-grade wall transformer. This device is a UL2601 listed wall transformer with an output of 12VDC and 500 mA max. There is also a 1A slow-blow fuse at the wall transformer input,(b) an industry standard DC-to-DC converter that meets the "dielectric withstand" and "leakage current" requirements of the UL2601 standard for Patient Care Equipment with isolated patient leads, and (c) the opto-isolation couplers described in Data Acquisition below.

Data Acquisition / RS232 Data Link: Processed signals are converted from analog voltages to 12 bit digital values by the analog-to-digital converter (ADC). The digital data is sent to and from the serial port of the PC across the isolation barrier via opto-coupler devices. The ADC and a portion of the RSR232 data link are on the patient side of the isolation barrier. The proper use of high voltage opto-couplers provides the dielectric withstand and low leakage current characteristics specified in UL2601. The non-isolated sides of the opto-couplers are then routed to RS232 drivers and receivers which are, in turn, routed to a DB9 connector at the rear panel of the Instrument Console. A standard RS232 serial cable connects the Instrument Console to the PC serial port.

Section 7: Conclusion

The Insight Millennium Plus is substantially equivalent to the two predicate devices. Furthermore, the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Mr. Lee Brody
Fasstech
155 Middlesex Turnpike
Burlington, Massachusetts 01803

Re: K011964
Trade/Device Name: Insight Millenium Plus
Regulation Number: 882.5050
Regulation Name: Biofeedback device
Regulatory Class: II
Product Code: HCC, HRW
Dated: June 22, 2001
Received: June 25, 2001

Dear Mr. Brody:

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 such 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). 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,

Susan Walker MS

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

Enclosure

510(k) Number (if known): K011964

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Device

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011964