DEC 4 1998

K982995

II 510(k) Summary

2.0 General

In accordance with the Safe Medical Devices Act of 1990 (SMDA), this section is a summary of the safety and effectiveness information for this premarket notification upon which an equivalence determination could be based (510(k) summary) [21 CFR ξ 807.3].

2.1 Submitter Information

Applicant: ..... KORR Medical Technologies, Inc.

Contact:..... Scott A. Kofoed

Address:..... 3090 East 3300 South Suite 3B
Salt Lake City, UT 84109

Phone:..... (801) 483-2080

Fax:..... (801) 483-2123

Date Prepared:..... Friday, August 21, 1998

Trade name: ..... ACCUTRAX Electronic Peak Flow Meter

Common Name: ..... Peak Flow Meter

Model: EPF840

Classification name: ..... Meter, Peak Flow, Spirometry

Product Code: ..... AN-BZH

CFR Section: ..... 21 CFR ξ 868.1860

Classification: ..... Class II

Predicate Device: ..... Vitalograph 2110 Electronic Flow Meter
510(k) Number: K943678

2.2 Device Description

The EPF840 is an electronic PEF/FEV_1 monitor. It can store PEF/FEV_1 test results, symptom scoring, and inhaler usage with a time and date stamp. The physician may retrieve data for analysis and trending using a personal computer. The physician may customize color zone indicators to the patient's needs.

2.3 Intended Use

This AccuTrax EPF840device is intended for monitoring PEF and FEV_1 for patient home and work use. The EPF840 is designed for pediatric to adult patients. The simple device interface provides ease of use for pediatric patients. When the EPF840 is used to watch lung conditions such as asthma, the user should be under the care of a licensed health care professional. A licensed health care professional's advise is required to understand the meaning and importance of the measures reported by the AccuTrax 840, and how to decide on an appropriate treatment plan. This treatment plan will tell you what action to take when there are changes in your PEF/FEV_1 numbers.

The product literature contains the text, "*CAUTION: Federal Law restricts this device to sale by or on the order of a physician*."

2.4 Technical Comparison to Predicate Device

	Parameter Compared	ACCUTRAX Model EPF840	Predicate Device (2110)	Difference Between
1	Manufacture	KORR Medical Technologies	Vitalograph	
2	Model Name	AccuTrax Model EPF840 electronic Peak Flow Meter	2110 electronic PEF/FEV_1 Diary	
3	FDA Number	(pending)	K943678	
4	Parameters Measured	PEF FEV1	PEF FEV1	No difference
5	Flowhead			
	Flow detection principle	Air pressure reducing mess in a flow head is applied to a pressure transducer.	Air pressure reducing mess in a flow head is applied to a pressure transducer.	No difference
	Back pressure	< 1.5 cmH2O / Liter / second (complies with ATS standards)	< 1.5 cmH2O / Liter / second (complies with ATS standards)	No difference
	Cleaning	Single patient use. Clean with warm soapy water daily. Disposable.	Cold liquid recommended or disposable.	The EPF840 does not recommend could liquid sterilization since it has not been verified or validated on this device.
6	Volume measurement	Flow integration	Flow integration	No difference
7	Maximum recorded flow rate	875 L/minute	999 Liter/minute	2110 reports higher flow rate. Both devices above ATS standard.
8	Maximum recorded volume	8.50 Liter	9.99 Liter	2110 reports higher volume. both devices above ATS standard.
9	Volume measuring accuracy	± 5% or ± 0.100 L whichever is greater	± 3% or ± 0.050 L whichever is greater	The 2110 specification is that of the "diagnostic" recommendation for the ATS standard. The EPF840 is that of

	Parameter Compared	ACCUTRAX Model EPF840	Predicate Device (2110)	Difference Between
				the "monitoring" recommendation for the ATS standard.
10	flow measuring accuracy	± 10% or ± 24 L/min whichever is greater	± 5% or ± 12 L/min whichever is greater	The EPF specification is that of the recommendation of the ATS standard for "diagnostic" use. The 2110 predicate device did not test within the reported ± 5% tolerance during comparison testing on waveform #24.
11	Test duration	1 to 2 seconds	1 to 2 seconds	No difference
12	Back extrapolation	FEV1	FEV1	No difference
13	Good/Bad Test criteria	Best PEF value of three tests	Best two PEF values within 10%	The EPF840 stores only the values associated with the maneuver with the best PEF value.
14	Test acceptance criteria	Time to PEF < 300 msec	40msec < Time to PEF < 300 msec	The EPF840 does not require a minimum time to the peak flow value.
15	Correction Factors			
	BTPS	YES	YES	No difference
	Altitude	NO	NO	No difference
	Humidity	NO	NO	No Difference
16	# of Results stored	480 Tests	200 tests	The EPF840 stores more tests
17	Storage medium	Non-volatile EEPROM	Non-volatile EEPROM	No difference
18	Time/Date	Real-time clock	Real-time clock	No difference
19	Alert User Alarm	No alert alarms	up to 4 / day	The 2110 can be configured to "wake up" and alarm the user to use the device. The EPF840 can not.

	Parameter Compared	ACCUTRAX Model EPF840	Predicate Device (2110)	Difference Between
20	User Warnings			
	Low battery	YES	YES	No difference
	Memory low	NO	YES	EPF840 Uses a circular buffer where the oldest data is overwritten by the newest data.
	Memory full	NO	YES	EPF840 Uses a circular buffer where the oldest data is overwritten by the newest data.
	Alarm Type	LCD Display & Audible buzzer	LCD Display & Audible buzzer	No difference
21	Event marker	Time and date stamp	Time and date stamp	No difference
22	Symptom scoring	Text based configurable by physician	Numeric rating of symptoms	The EPF840 has a character based display which allows for text based symptom entry.
23	Result printing	NO	Serial to printer	No direct printing from EPF840
24	Results download	Serial to personal computer	Serial to personal computer	No difference
25	Color zones	3 zones	3 or 4 configurable zones	The 2110 also has a purple zone.
26	Device configuration	via PC	via PC or using device keys	The EPF840 does not allow setup directly using the device to prevent patient tampering.
27	Testing temperature	15 to 35 Degree C	17 to 35 Degree C	Similar range
28	Power source			
	Primary source	Alkaline 9-volt battery	Alkaline 9-volt battery	No difference
	RTC backup	Lithium 3V battery CR2032	Lithium 3V battery CR2032	No difference
29	Automatic power off	3 minutes	4 minutes	EPF840 shuts off 1 minute sooner. The

	Parameter Compared	ACCUTRAX Model EPF840	Predicate Device (2110)	Difference Between
				3 minute timer in the EPF840 is the time from the last key press or PEF maneuver.
30	Display	LCD	LCD	No difference
31	Keyboard	Tactile switches under a front panel overlay	Rubber membrane	Both switch technologies provide good environmental protection
32	Unit Dimensions	88 mm x 112 mm x 48mm	145mm x 70mm x 87mm	The EPF840 is slightly smaller
33	Unit weight	184g with battery	190g with battery	Weights are very similar
34	Materials			
	Flowhead	ABS, Cycolac 2502 (GE Plastics)	ABS, Magnum 3453	Both use ABS plastic
	Unit Body	ABS, Cycolac 2502 (GE Plastics)	ABS, Magnum 3453	Both use ABS plastic
	Flowhead to unit pneumatic connection	Silicone foam	Silicone rubber	The 2110 uses silicone rubber pre-formed tubing to pneumatically connect to the pressure transducer. The EPF840 uses a stamped silicone foam.

2.5 Non-clinical Performance Data

The ACCUTRAX EPF840 electronic peak flowmeter was tested at an independent laboratory using a precision waveform generator. The peak expiratory flow (PEF) and forced expiratory volume in one second (FEV1) measurements from the EPF840 were compared against the generated values. Both PEF and FEV1 values were well within the required ATS accuracy specifications using the 24 standard waveforms and the 26 flow-time waveforms. Inter-device and intra-device variability testing demonstrated the EPF840 to comply with all variability requirements. Our evaluation showed the EPF840 to be accurate and extremely repeatable in all tests

Both the EPF840 and the predicate device was tested using Waveform #24 using a range of scale factors. The generator multiplies each flow by the scale factor. PEF reported by the EPF 840 is compared to the values reported by the generator. The scale factors tested are 0.8, 1.0, 1.2, 1.6, 2.0, 2.4, 2.8, 3.0, 4.0, and 5.7.

Both devices operated within the 10% specification of the ATS standard for peak flow.

2.6 Clinical Data

Determination of substantial equivalence is not based on assessment of clinical data.

2.7 Substantial Equivalence Conclusion

Both devices demonstrate product safety by successful completion of testing to the IEC601-1 standard. The ACCUTRAX EPF840 successfully completed independent laboratory testing for electromagnetic compatibility to the IEC601-1-2 standard.

Both devices claim to meet the American Thoracic Society (ATS) recommendations for spirometry. Performance testing at LDS Hospital (Salt Lake City, UT) demonstrates that the EPF840 meets the ATS standard recommendations.

The following decision tree was used to determine if the EPF840 is substantially equivalent to the predicate device.

2.7.1 Does the new device have same indication statements?

Yes. The new device and the predicate device report the same parameters, namely; Peak Expired Flow Rate (PEF), and Forced expired volume (FEV_1).

Both devices have a red-yellow-green zone indication based upon the peak flow rate measured. The physician is required to setup the zone indications on both devices.

Both devices provide a means for the patient to enter symptom and medication usage.

2.7.2 Does the new device have same technological characteristics in design and materials?

Yes. Both devices use a pneumotach (flowhead) with fixed obstruction that generates a backpressure in response to the measured flow rate. Both

pneumotachs are made from ABS plastic. The enclosures are also ABS plastic. The mouthpiece on both devices has the same taper and outer diameter.

The measured pressure is used to calculate the flow rate. The flow rate is integrated to obtain volume. Both devices use a back extrapolation method to determine the start of the FEV_1 maneuver.

Both devices are powered from a 9-volt alkaline battery. Both devices use a CN3032 3-volt lithium battery to power the internal real-time clock.

Both devices store the FEV1/PEF values in non-volatile memory with a time and date stamp. On both devices, these data are available to the physician through a communication port adapter to a personal computer. On both devices the communication connector is a modular 4 pin connector located under the battery door.

2.7.3 Are the descriptive characteristics precise enough to ensure equivalence?

No. Performance data is also required.

2.7.4 Are performance data available to assess equivalence?

Yes. The new device was tested to and passed the ATS standard waveforms using a waveform generator.

2.7.5 Does performance data demonstrate equivalence?

Yes. Both devices meet ATS standards for monitoring devices.

2.7.6 Substantially equivalent determination:

From the above information we conclude that the new device (ACCUTRAX EPF840) is substantially equivalent to the predicate device (Vitalograph 2110 Electronic Flow Meter)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

Mr. Scott A. Kofoed
Korr Medical Technologies, Inc.
3090 East 3300 South, Suite 3B
Salt Lake City, UT 84109

Re: K982995
AccuTrax Model EPF840
Regulatory Class: II (two)
Product Code: 73 BZH
Dated: November 3, 1998
Received: November 6, 1998

Dear Mr. Kofoed:

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 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). 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 requirements, 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) 594-4648. 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 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Intended Use

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The product literature contains the text, "*CAUTION: Federal Law restricts this device to sale by or on the order of a physician.*"

Mark Kramer

PRESCRIPTION USE X OR OVER THE COUNTER USE _____