3/12/99

K983355

Section 2
Summary

The following is a Summary of the Sabratek APM-2000 Ambulatory Patient Transcutaneous Temperature Monitor substantial equivalence and safety and efficacy.

CLASSIFICATION NAME: Clinical electronic thermometer

COMMON/USUAL NAME: Electronic thermometer

PROPRIETARY NAME: Sabratek Corporation, APM-2000 Ambulatory Patient Transcutaneous Temperature (TcT) Monitor

CLASSIFICATION: 21 CFR Part 880.2910 Clinical electronic thermometer

PERFORMANCE STANDARDS: No Performance Standards are in effect for this device.

PREDICATED DEVICE Diatek Thermometer, K833568, and Deep Body Thermometers Limited, pre 1976 device.

Parameter	Sabratek Transcutaneous Temperature	Deep Body Thermometers Limited	Diatek Digital Thermometer
Intended Use	Patient body temperature	Patient body temperature	Patient temperature
Temperature Range	90°F (31.9° C) – 106°F (40.7° C)	78.8° F (26° c) – 107.6° F (42° C)	Full Range Unknown
Display Type	Digital	Digital	Digital
Display Resolution	± 0.1 F	± 0.1 C	± 0.1 C
Warm-up Time	30 Minutes	30 Minutes	30 Minutes
Accuracy	0.3° F over range of 95° F - 105° F	0.3° C	0.3° C
Counts Up and Down	Yes	Yes	Up only
Ambient Temperature environment	Less than temperature being taken	Less than temperature being taken	Less than temperature being taken
Skin surface probe	Yes	Yes	Mouth or arm pit
Power Supply	Battery	Battery or Mains	Battery

Battery Charger	No	Yes	Yes
Single Patient Probe	Yes	Yes	Yes
Shipped Sterile	No	No	No
Microprocessor	No	No	Unknown
Alarms	No	No	No
FDA "K" Number		Pre 1976 device	K833568

INDICATIONS

Measures and displays long-term "body temperature" as calibrated to the equivalent oral temperature standard.

CONTRAINDICATIONS

Will not provide valid data in ambient temperatures greater than patient body temperature.
Requires 30 minute warm-up before achieving accurate readings.
Will not operate while exposed directly to sun or other forms of radiant heat.

NON-CLINICAL TEST

Non-clinical tests included comparison with temperature standard.

CONCLUSIONS

The Sabratek Corporation, APM-2000 Ambulatory Patient Transcutaneous Temperature Monitor is equivalent in safety and efficacy to its predicate devices.

Sabratek Corporation
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847-720-2400
847-647-2382 Facsimile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Mr. Edward F. Waddell
Director of Regulatory Affairs and Quality Assurance
Sabratek Corporation
5601 West Howard
Niles, IL 60714

Re: K983355
Sabratek APM-2000 Ambulatory Patient Transcutaneous Temperature Monitor (TcT) for the Sabratek APM-2000
Regulatory Class: II (two)
Product Code: FLL
Dated: January 21, 1999
Received: January 22, 1999

Dear Mr. Waddell:

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

510(k) Number K983355

Device Name: Sabratek, Corporation. APM-2000 Ambulatory Patient Transcutaneous Temperature Monitor

Indications for use: Measures and displays patient temperature as calibrated to the equivalent oral temperature standard. The APM-2000 Ambulatory Patient Transcutaneous Temperature Monitor is an element of the Sabratek Corporation APM-2000 System.

Prescription Device. Federal Law (US) restricts this device to sale by or on the order of a physician.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983355

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)