

510K SUMMARY OF SAFETY & EFFECTIVENESS

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

The assigned 510K number is: 16992874

NOV 18 1999

APPLICANT INFORMATION:

WR Medical Electronics Co.
123 North Second Street
Stillwater, MN 55082 USA
Tel: 651-430-1200
Fax: 651-439-9733
Attn: Patrick J. Anderson, President

DEVICE INFORMATION:

Trade Name: Q-Sweat Quantitative Sweat Measurement System

Common Name: Evaporimeter, Evaporative Water Loss Device, Hydrograph, Trans Epidermal Water Loss (TEWL) Device, or Sweat Measuring Device

EQUIVALENT DEVICE:

Predicate Device No. 1: Abrams Model WVD-101 Evaporative Water Loss Instrument, 1322 Rensen Street, Lansing, MI 48910-3688

Predicate Device No. 2: (Pre-Amendment) Servo-Med Evaporimeters EP1C and EP1D, Box 110, S-162 12 Stockholm, Sweden, or Box 129, Ikinna, Sweden

Predicate Device No. 3: DermaLab TEWL Device, Cortex Technologies, Smedevaenget 10 9560 Hadsund, Denmark

Predicate Device No. 4: Tewameter TM 210, ACA Derm, 120 Independence, Menlo Park, CA 94025

DEVICE DESCRIPTION:

The Q-Sweat device is measurement-only device which is designed to measure the rate & volume of sweating by capturing a sample of sweat (water) inside a small measuring chamber which is affixed to the skin. It does not measure any other parameters of the sweat sample. The measurement made is simply a calculation of moisture given off by the skin.

INTENDED USE:

The Q-Sweat™ Quantitative Sweat Measurement System is designed to measure the sweat output of the skin of humans. This device does not make a diagnosis or indicate by itself that any disease state exists; it simply documents sweat output. This device is to be used in scientific studies of the anatomy, physiology, and biochemistry of the skin & associated structures.

COMPARISON TO PREDICATE DEVICE:

WR Medical Electronics Co. claims substantial equivalence to several devices that are used for measuring the rate of sweating from the skin of humans. The use of the Q-Sweat device on a human does not effect the body any differently than the use of the predicate devices on humans; nor does the use of the Q-Sweat raise any new questions of safety or effectiveness. The Q-Sweat device operates in the nearly exact same fashion as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 18 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Patrick J. Anderson
President
WR Medical Electronics Company
123 North Second Street
Stillwater, Minnesota 55082

Re: K992874
Trade Name: Q-Sweat Quantitative Sweat
Measurement System
Regulatory Class: II
Product Code: KTB
Dated: August 23, 1999
Received: August 26, 1999

Dear Mr. Anderson:

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.

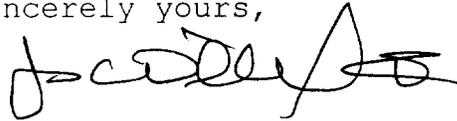
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Patrick J. Anderson

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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K992874

DEVICE NAME: Q-SWEAT™ QUANTITATIVE SWEAT MEASUREMENT SYSTEM

INDICATIONS FOR USE:

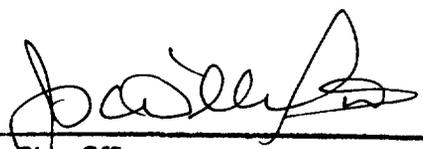
The Q-Sweat™ Quantitative Sweat Measurement System is designed to measure the sweat output of the skin of humans. This device does not make a diagnosis or indicate by itself that any disease state exists; it simply documents sweat output.

(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 _____

K992874