

MAY 28 1998



Section 2: 510(k) Summary or Statement

K974285

2.1. 510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Assigned 510(k) no.: _____

Applicant/Contact: Kjell Bakken*, President, Perimed Inc and Perimed AB.

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Date Prepared: 20/10/97

Classification Name: Laser Doppler Flowmeter (Blood Flow Meter).

Common/Usual Name: Laser Doppler Flowmeter

Trade/Proprietary Name: PeriFlux System 5000 Modular Laser Doppler Flowmeter, including: PF 5001 Main Unit, PF 5010 LDPM Unit, PF 5990 Blank Panel", PeriSoft Analysis Software and 400-series Probes.

Predicate Device: PeriFlux PF 4001 Laser Doppler Flowmeter: K 922368, plus additional probes: K935495.

Device description: PeriFlux System 5000 Modular Laser Doppler Flowmeter System 5000 consists of a PF 5001 Main Unit, which can accommodate up to four Function Units. The first available Function Unit is the PF 5010 LDPM (Laser Doppler Perfusion Monitor) Unit. A PF 5990 Blank Panel takes the place of a Function Unit if less than four Units are required. Probes are attached to collect the information, which is analysed, using the PeriSoft analysis program.

Intended Use: The PeriFlux System 5000 is indicated for use in measuring microvascular perfusion, in skin and muscle, in humans. It is also indicated for use in measuring microvascular perfusion in all tissues in animals.

Summary of the technological characteristics of the PeriFlux System 5000 compared with the PeriFlux System 4000:

The PeriFlux System 5000 Modular Laser Doppler Flowmeter is developed directly from the PeriFlux System 4000. The technology is the same but the design has been modified to simplify use of the instrument and allow customers to more easily choose the number of channels they need.

Whereas the PeriFlux System 4000 presented the parameters Perfusion, CMBC (Concentration of Moving Blood Cells), Velocity and TB (Total Backscatter) to the user the PeriFlux System 5000 presents only Perfusion and TB (CMBC and Velocity are measured by the instrument to calculate Perfusion).

The probes which are used with the PF 5010 LDPM Unit are identical in every way with those used for the PeriFlux System 4000 laser Doppler Flowmeter - they are interchangeable between the two systems.



MAY 28 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kjell Bakken
President
Perimed, Inc.
821 West Jericho Turnpike
Suite A
Smithtown, NY 11787

Re: K974285
PeriFlux System 5000 Modular Laser Doppler Flowmeter
Regulatory Class: II (Two)
Product Code: DPW
Dated: May 2, 1998
Received: May 7, 1998

Dear Mr. Bakken:

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 (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.

Page 2 - Mr. Kjell Bakken

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" (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,



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 (if known): K 974285

Device Name: PeriFlux System 5000

Indications For Use:

The PeriFlux System 5000 is indicated for use in measuring microvascular perfusion, in skin and muscle, in humans. It is also indicated for use in measuring microvascular perfusion in all tissues in animals.

(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 K 974285

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____