NOV 0 7 2001

Premarket Notification 510(k) Summary

K011070

Company Name:	MOOR INSTRUMENTS LIMITED
Address:	MILLWEY AXMINSTER DEVON EX13 5HU ENGLAND
Telephone No:	+44 (0)1297 35715
Fax No:	+44 (0)1297 35716
Contact Name:	DAVE BOGGETT
Contact Title:	MANAGING DIRECTOR
Date:	30/03/2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Dr. David M. Boggett
Managing Director
Moor Instruments, Ltd.
Millwey, Axminster
Devon EX13 5HU
England

Re: K011070
Trade/Device Name: DRT4 Laser Doppler Perfusion and Temperature Monitor
Regulation Number: 878.4810, 870.2100
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Cardiovascular blood flowmeter
Regulatory Class: II
Product Code: GEX, FIT
Dated: August 7, 2001
Received: August 9, 2001

Dear Dr. Boggett:

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.

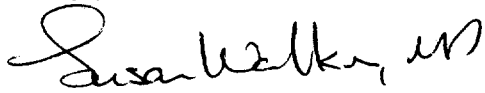
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

K011070/A1

NOV 0 7 2001

510 (k) Number K011070

DEVICE NAME: DRT4 LASER DOPPLER PERFUSION AND TEMPERATURE MONITOR

INDICATIONS FOR USE:

The DRT4 laser Doppler Perfusion and Temperature monitor is intended for blood flow measurements, e.g. blood flow in the small vessels of the skin. It is suitable for a wide range of clinical research applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology , neurosurgery and anaesthetics.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrance of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) or Over-The-Counter-Use _____ (Optional Format 1-2-96)

Susan Walker

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

510(k) Number K011070