Moor Instruments Ltd

DEC 1 0 2003

EDICAL AND OPTO-ELECTRONIC INSTRUMENTATION

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K032841

Premarket Notification 510(k) Summary

Company Name:	MOOR INSTRUMENTS LIMITED
Address:	MILLWEY AXMINSTER, DEVON U.K. EX13 5HU
Telephone No:	+44 (0)1297 35715
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Contact Name:	DAVE BOGGETT
Contact Title:	Managing Director
Date:	02/12/2003

510(k) Summary K032841

Classification Name:	Blood Flow, Cardiovascular Product Code: DPT CFR Section: 870.2120
Common/Usual Name:	Laser Doppler Perfusion Imager
Trade/Proprietary Name:	moorLDI2-IR Infrared Laser Doppler Imager
Establishment Registration No:	8043564
Classification:	Regulatory Class II
Performance Standard:	The equipment conforms to IEC 825:1:1993 + A1:1997 + A2:2001 Class 3R Medical Laser Product as per IEC 825:1:1993 + A1:1997 + A2:2001 The equipment complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50. Dated July 26, 2001
Reason for Submission:	New Device
Predicate Devices:	moorLDI Laser Doppler Perfusion Imager 510(k) Number - K980383

Description of the Device

The moorLDI2-IR infrared laser Doppler imager is a device for imaging blood flow in the microcirculation. It uses the established laser Doppler technique to quantify movement of blood cells beneath the skin surface. Unlike the existing MK1 moorLDI laser Doppler imager, which use a low power visible red HeNe laser, the moorLDI2-IR has a low power infrared laser beam combined with a visible target beam to scan in a raster pattern over the skin surface to build up a colour coded image of blood flow.

Intended Use

The moorLDI2-IR infrared Laser Doppler Imager is intended for blood flow measurements in the microcirculation.

Technological Characteristics

- **moorLDI2-IR Compared with moorLDI Laser Doppler Imager**

The operation and design of the moorLDI2-IR infrared laser Doppler image is based on the predicate device moorLDI. They both have the same intended use. Both devices rely on the same physical principle, i.e. the laser Doppler principle, to measure the tissue blood perfusion. Both instruments scan a low power laser beam over the tissue surface in a raster pattern to produce a two dimensional colour coded blood perfusion image. The main differences between two devices are the laser sources and inclusion of colour video camera in the moorLDI2-IR.

However, the potential hazards due to use of a near infrared laser source is not considered to compromise the safety of the instrument since the moorLDI2-IR has been designed to comply with all related safety standards and has implemented the extra safety precautions such as beam attenuator, visible aiming beam and infrared emission indicator to reduce the risks to an acceptable level.

Performance Data

In order to evaluate the performance of the moorLD2-IR infrared laser Doppler perfusion imager, and determine its substantial equivalence to the predicate device moorLDI, a set of comparison tests has been carried out. These include flow model, single point measurement and image scan using both devices. The results suggest that moorLDI2-IR has achieved the same performance as the predicate device moorLDI laser Doppler imager.

Conclusions

From the description of the technological characteristics and the performance data, it can be concluded that the moorLDI2-IR infrared laser Doppler imager is substantial equivalence to the predicate device moorLDI in terms of effectiveness and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2003

Dr. David Boggett
Managing Director
Moor Instrument Ltd
Millwey
Axminster
Devon, EX 13 5HU
United Kingdom

Re: K032841
Trade/Device Name: moorLD12-IR Infrared Laser Doppler Imager
Regulation Number: 21 CFR 870.2120, 21 CFR 878.4810
Regulation Name: Extravascular blood flow probe; Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: DPT, GEX
Dated: September 5, 2003
Received: September 11, 2003

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Miriam C. Provost

for 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

Indications for Use

510(k) Number (if known): K 032841

Device Name: moorLDI2-IR Infrared Laser Doppler Imager

Indications For Use:

The moorLDI2-IR infrared laser Doppler Imager is intended for blood flow measurements in the microcirculation.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032841