K060976

510(k) Summary

Company Name: MOOR INSTRUMENTS LIMITED

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Contact Name: DAVID BOGGETT

Contact Title: Managing Director

Date: 9th August 2006

Classification Name: Blood Flow, Cardiovascular
Product Code: DPT, GEX
Regulation Number: 21 CFR 870.2120 /
21 CFR 878.4210

Common/Usual Name: moorLDI Burns Imager

Trade/Proprietary Name: moorLDI2-BI Laser Doppler Burns Imager

Establishment Registration No: 8043564

Classification: Regulatory Class II

Performance Standards: The equipment conforms to:-

1. Medical Electrical Equipment as per BS EN 60601-1:1990
2. Class 3R Medical Laser Product as per IEC 825:1:1993 + A1:1997 + A2:2001
3. 21 CFR 1040:10 and 1040:11 Except for deviations pursuant to Laser Notice No. 50 Dated July 26, 2001
4. Electromagnetic Compatibility Requirements and Tests as per BS EN 60601-1-2:1993 including AMD10002 1998
5. General Requirements for Programmable Electrical Medical Systems as per BS EN 60601-1-4:1997
6. Medical Electrical Equipment Part 1: General Requirements for Safety as per UL 2601-1:2003

Reason for Submission: Additional or expanded indications

Predicate Devices: moorLDI Laser Doppler Blood Flow Imager 510(k) K980383
moorLDI2-IR Infrared laser Doppler Imager 510(k) K032841

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Description of the Device:

The moorLDI2-BI laser Doppler imager is a measurement device to aid the clinician judge the healing potential of burns and the need for surgery.

It uses the laser Doppler technique to quantify the blood flow in an area of skin damaged by a burn. The device has the means to scan a low power visible red laser beam or low power near infrared laser beam combined with a visible red target beam, across the skin surface enabling a colour coded image of the blood flow in the burn area and the surrounding normal skin to be recorded, together with a monochrome photo image. In addition, a colour video image of the scanned area is recorded using a CCD camera which is an integral part of the device.

Regions of interest (e.g. a burn area) can be selected and the statistics of the blood flow values, within the region, calculated and displayed.

Intended Use

The moorLDI2-BI laser Doppler burns imager assesses the blood flow in debrided burn wounds of the skin. It is intended to be used as an aid to burn wound management for patients with Total Body Surface Area burn of up to 30%.

Technological Characteristics

The operation and design of the moorLDI2-BI laser Doppler burns imager is based on the predicate moorLDI and moorLDI2-IR laser Doppler imagers.

The burns imager laser light source is either:-

a Helium Neon red gas laser as used in the moorLDI or
a visible red laser diode as used in the moorLDI2-VR or
a near infrared laser diode with visible red target beam as used in the moorLDI2-IR.

(Note that the moorLDI2-VR differs from the moorLDI2-IR in that it has a visible red laser diode rather than a near infrared laser diode).

The burns imager with the near infrared laser has identical hardware to that of the moorLDI2-IR.

The design and construction of the electronics and the basic optics are the same for all three imagers. The instrument case for the burns imager is the same as that of the moorLDI2-IR except for the colour and the labelling of the front panel.

The main difference between the devices is the PC software for image display and processing.

The PC software for the moorLDI2-BI is designed specifically for the recording and measurement of blood flow in skin burns. The range of instrument settings and image processing operations is limited to those appropriate for aiding the clinician in assessing the healing potential of a burn wound. The PC software for the moorLDI and moorLDI2-IR is designed for research applications where a wide range of instrument settings are needed to investigate blood flow in the microcirculation of skin and other organs. The moorLDI and the

moorLDI2-IR has been used over a number of years for measurement and recording of blood flow in skin burns and reports have been published in international journals.

The moorLDI2-BI and it's predicate devices are calibrated identically and use the same blood perfusion units.

Performance Data

The moorLDI2-BI is manufactured to the same design as the moorLDI and moorLDI2-IR.

It has the same test and performance specifications.

The use of the moorLDI, the moorLDI2-VR and moorLDI2-IR imagers to assess the healing potential of a burn has been investigate over a 3 year period, from 2001 to 2004, by a group of experienced burns surgeons working in 5 hospital burns centres.

They have identified and quantified three laser Doppler blood flow ranges (high, medium and low) which allow an experienced burns surgeon to predict the healing potential of a burn (healing in <14 days, 14-21 days and > 21 days) to better than 90% accuracy after confounding factors such as wound infection, etc. are taken into account. The moorLDI2-BI PC software uses a colour palette for blood flow images based on the results of this clinical investigate which can be used by a trained operator (a burns surgeon or under the direction of a burns surgeon) as an aid to predicting healing potential and hence the need, or not, for surgery.

The moorLDI2-BI blood flow images of burns and/or their interpretation can be adversely influenced by a number of factors: these **must** be considered during assessment. These are referred to as confounding factors: un-debrided skin/debris/eye coverings, infection, medication/sickness, edge effect, high reflection, scan too soon after debridement, and scan after day 5,

Conclusions

The moorLDI2-BI is substantially equivalent to the predicate devices in terms of technological characteristics and performance.

All three devices can be used to image burns. The moorLDI2-BI uses PC software specifically designed for imaging in a clinical environment and assessing blood flow in burn damaged skin in order to predict healing potential.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Moor Instruments Limited
% Mr. David Boggett
Managing Director
Millwey, Axminster
Devon EX13 5HU UK

MAR 2 7 2007

Re: K060976
Trade/Device Name: moorLD12-BI Laser Doppler Burns Imager
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: Class II
Product Code: DPT, GEX
Dated: March 16, 2007
Received: March 20, 2007

Dear Mr. 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for P. Lohr

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060976

Indications for Use Statement

510(k) Number: K060976

Device name: moorLDI2-BI Laser Doppler Burns Imager

Indications for use:

The moorLDI2-BI laser Doppler burns imager assesses the blood flow in debrided burn wounds of the skin. It is intended to be used as an aid to burn wound management for patients with Total Body Surface Area burn of up to 30%.

Prescription Use: Yes (Part 21 CFR 801 SubpartD)	AND/OR	Over-The-Counter Use: No (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060976