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5 moorLDLS-BI 510(k) Summary

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Date:	July 1, 2013
Model Name:	moorLDLS-BI Laser Doppler Burns Imager
Model Number:	moorLDLS-BI
Common Name:	Laser Doppler Burns Imager
Classification Name:	Extravascular blood flow probe, DPT, 21 CFR 870.2120 Laser surgical instrument for use in general and plastic surgery and in dermatology, GEX, 21 CFR 878.4810
Regulatory Status:	Class II
Establishment Reg No:	8043564
Type of 510(k):	Traditional
Reason for submission:	New Device
Predicate Device:	moorLDI2-BI Laser Doppler Burns Imager

510(k) Number K060976

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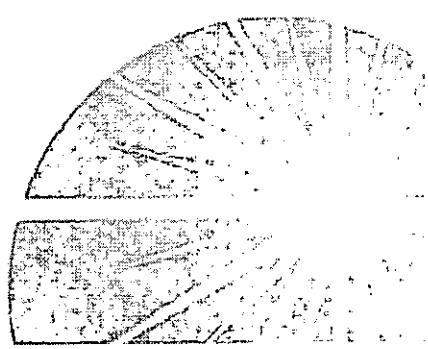

Description of the Device

The moorLDLS-BI laser Doppler burns imager is an imaging device to aid the clinician to judge the healing potential of burns and the need for surgery.

It uses the laser Doppler imaging technique to quantify the blood flow in an area of skin damaged by a burn. The device uses a line of laser light projected onto the tissue and a linear detector array that sample from the line as it is swept across the tissue to rapidly build up a colour coded image of blood flow in the burn area and the surrounding normal skin for healing potential prediction. In addition, a CCD camera is integrated into the scanner unit for recording a colour photograph at the time of scanning, corresponding closely with the blood flow image in size and aspect.

Intended Use

The moorLDLS-BI laser Doppler burns imager assesses the blood flow in burn wounds of the skin, when cleaned of surface debris, to aid in the clinician's assessment of burn wound healing potential. 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%.

The device is intended to be used as an aid to burn wound assessment, and not as a stand-alone prediction device.

Substantial Equivalence

Technological Characteristics

The operation and design of the moorLDLS-BI laser Doppler burns imager and the predicate device moorLDI2-BI are very similar. Both devices rely on the same physical principle, i.e. the laser Doppler imaging technology, to measure the tissue blood perfusion for healing potential prediction of burn wounds. The moorLDLS-BI uses the same dedicate colour palette as the predicate device to predict three types of burn wound healing potentials, i.e. **HP14**: healing in <14 days, **HP14-21**: healing in 14-21 days and **HP>21**: healing in > 21 days.

The main difference between two devices is the scanning method. The predicate device moorLDI2-BI scans a low power laser beam (single laser spot) over the tissue surface in a raster pattern to produce a two dimensional colour coded blood perfusion image, while the moorLDLS-BI laser Doppler burns imager uses a low power laser line to sweep across the tissue for rapid scanning which could be important in clinical environment to minimize scan time and patient discomfort.

Indication for Use

Both devices have the same intended use, i.e. assessing the blood flow in debrided burn wounds of the skin and to be used as an aid to burn wound management for patients with burn wounds.

Both devices are intended to be used within the hospital environments by burns surgeons for the same patient population, i.e. patients with burn wounds at 48 hours to 5 days post-burn.

Performance Data

The moorLDLS-BI burns imager has been designed and tested for compliance with the standards for electrical safety, laser radiation safety, electromagnetic compatibility and programmable medical device.

To establish the substantial equivalent between the predicate device and new device for the effectiveness of burns assessment, two types of performance bench testing and a clinical investigation have been carried out. The bench testing includes a flow model experiment and image scan of normal skin tissue using both devices. The results show that the moorLDLS-BI and the predicate device have a good correlation for tissue blood flow measurement.

A multi-centre clinical investigation entitled 'Clinical Investigation of the moorLDLS-BI for Burn Healing Potential Assessment' was conducted in five burns centres (2 in the UK, 1 in the USA, 1 in the Belgium, 1 in the Australia).

The objectives of this clinical investigation were

1. To assess the performance and accuracy of a new moorLDLS-BI line scan burns imager for prediction of burn wound healing potential;
2. To compare the performance of the moorLDLS-BI with the predicate device moorLDI2-BI burns imager.

The clinical investigation of the performance and accuracy for burns assessment using both devices has been performed on 596 burns cases for 204 burns patients. An overall accuracy of 94.2% was found for moorLDLS-BI when compared with healing records. The agreement between the moorLDLS-BI and moorLDI2-BI as the non-reference stand was 95.4% for HP14, 94.2% for HP14-21 and 98.5% for HP>21.

A specific analysis of non-inferiority was performed and found that the moorLDLS-BI is unlikely to perform more than 1.7% worse than the predicate device moorLDI2-BI. In fact, the moorLDLS-BI performed slightly better than the moorLDI2-BI for these data, so there may well be no drop in accuracy at all.

The laser Doppler blood flow images of burns and/or their interpretation can be adversely influenced by a number of factors: these **must** be considered during image interpretation. These are referred to as patient and technical related confounding factors such as un-debrided skin, infection, medication/sickness, Tattoos, edge effect, high reflection, and movement artefact;

Conclusions

Based on the indications for use, design, technology, performance and functional testing, and clinical evaluation, it can be concluded that the moorLDLS-BI laser Doppler burns imager is substantial equivalent to the predicate device moorLDI2-BI as an aid to assessing healing potential in burn damaged skin in terms of effectiveness and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Moor Instruments Ltd.
Xiabing Huang
Managing Director
Millwey, Axminster
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UNITED KINGDOM

January 29, 2014

Re: K132163
Trade/Device Name: MoorLDLS-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: December 12, 2013
Received: December 26, 2013

Dear Dr. Huang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number: K132163

Device Name: moorLDLS-BI Laser Doppler Burns Imager

Indications For Use:

The moorLDLS-BI laser Doppler burns imager assesses the blood flow in burn wounds of the skin, when cleaned of surface debris, to aid in the clinician's assessment of burn wound healing potential. 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)

Neil R Ogden -S
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(Division Sign-off) for BSA

Division of Surgical Devices

510(k) Number K132163