DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 12, 2016

Moor Instruments Ltd
Stewart Lillington
Product Development Manager
Millwey Rise
Axminster, EX13 5HU GB

Re: K152749
Trade/Device Name: moorLDI2-IR Infrared Laser Doppler Imager,
moorLDI2-HIR High Resolution Infrared Laser Doppler Imager,
moorLDI2-VR Visible Red Laser Doppler Imager
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular Blood Flow Probe
Regulatory Class: Class II
Product Code: DPT, GEX
Dated: April 6, 2016
Received: April 13, 2016

Dear Stewart Lillington:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 *See PRA Statement below.*

510(k) Number *(if known)*
K152749

Device Name
moorLDI2 Laser Doppler Imager

Indications for Use *(Describe)*
The moorLDI2 Laser Doppler Imager is intended for blood flow measurements in the microcirculation. It is intended to be used for clinical research applications and pre-clinical research applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

moor instruments
innovation in microvascular assessment

5 510(k) Summary

5.1 Submitter Information:

Type of 510(k):	Traditional
Submitter:	Moor Instruments Ltd
Establishment Reg No:	8043564
Address:	Millwey, Axminster, Devon, EX13 5HU, United Kingdom
Telephone:	(+44) 1297 35715
Fax:	(+44) 1297 35716
Contact:	Stewart Lillington
Contact title:	Product Development Manager
E-mail:	lillington@moor.co.uk
Date:	September 17th, 2015

Device Information:

Trade Names:	moorLDI2-IR	(moorLDI2 Infrared laser Doppler imager)
	moorLDI2-HIR	(moorLDI2 High resolution infrared laser Doppler imager)
	moorLDI2-VR	(moorLDI2 Visible red laser Doppler imager)
Common Name:	moorLDI2 laser Doppler imager	
Classification Name:	Extravascular blood flow probe (21 CFR 870.2120, Product code DPT) Powered laser surgical instrument (21 CFR 878.4810, Product Code GEX)	
Predicate Device:	moorLDI2-IR laser Doppler imager 510(k) Number - K032841 Product codes DPT & GEX	

5.2 Device information

Trade names:	moorLDI2-IR	(moorLDI2 Infrared laser Doppler imager)
	moorLDI2-HIR	(moorLDI2 High resolution infrared laser Doppler imager)
	moorLDI2-VR	(moorLDI2 Visible red laser Doppler imager)
Common Name:	moorLDI2 laser Doppler imager	
Classification Name:	Extravascular blood flow probe (21 CFR 870.2120, Product code DPT)	
	Powered laser surgical instrument (21 CFR 878.4810, Product Code GEX)	
Predicate Device:	moorLDI2-IR laser Doppler imager 510(k) Number - K032841	

5.3 Description of the device

The moorLDI2 is a device to perform non-invasive blood flow measurements in the microcirculation, for example skin, using the established laser Doppler technique to quantify movement of blood cells beneath the skin surface.

Laser Doppler Imaging (LDI) is a technique first established commercially in the early 1990's and as such published studies now cover numerous pre-clinical, clinical research and clinical applications.

The system scans a very low power laser beam across the tissue. Moving blood in the microvasculature causes a Doppler frequency shift of the laser light, which is photo detected and processed to generate a colour coded blood flow map, line by line. An in built CCD camera records a colour photograph to aid visualisation of the scan site.

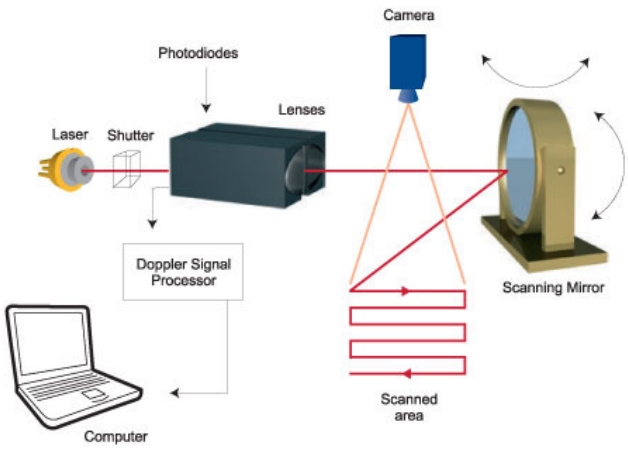


Figure 1. Principle of operation

The moorLDI2 laser Doppler imager scan head case consists of two injection moulded parts. Additionally a detachable injection moulded connector cover covers the external connectors in normal use. All injection moulded components are manufactured using Sika Biresin RG53 FR resin which is flame retardant to UL 94-V0. The enclosure has a cream coloured painted finish.

Figure 2. moorLDI2 fitted to Desktop Stand (DS2)

There are 3 moorLDI2 variants based upon the same design, moorLDI2-VR, moorLDI2-IR and moorLDI2-HIR. The key differences are shown in Table 1. In all other respects the three instruments are essentially identical in terms of their design and construction. Where differences between the instruments are not significant, they are collectively referred to using the generic term “moorLDI2”.

Model	**moorLDI2-VR**	**moorLDI2-IR**		**moorLDI2-HIR**	
Laser type	Helium Neon gas laser	Infra-red laser diode	Visible red laser diode	Infra-red laser diode	Visible red laser diode
Wavelength	633nm	785nm	658nm	785nm	658nm
Maximum output power	2.5mW	2.35mW	130µW	1.5mW	130µW
Beam diameter ($1/e^2$ points)	1.2mm	1.2mm		0.7mm minimum (25cm from scan head)	
Beam divergence	1.4milliradians			2.6milliradians	
Scan Area (20cm Distance)	(Normal area): 6.6cm x 6.6cm (Large area): 13cm x 13cm			(Normal area): 2.5cm x 2.5cm (Large area): 5cm x 5cm	
Scan Area (100cm Distance)	(Normal area): 25cm x 25cm (Large area): 50cm x 50cm			(Normal area): 9.4cm x 9.4cm (Large area): 18.8cm x 18.8cm	

Table 1

The physical and performance characteristics of the moorLDI2 laser Doppler imager are summarised in Table 1 and Table 2:

Measured Parameters	***Flux (Tissue perfusion)*** Range: 0-5000 PU Accuracy: ±10% relative to Moor Instruments 'standard' moorLDI Precision: ±3% of measurement from temperature controlled (22 ±1°C) motility standard ***Conc (Concentration of blood flow)*** Range: 0-5000 AU Accuracy: ±10% Precision: ±3% of measurement value ***DC (Intensity)*** Range: 0-5000 AU Accuracy: ±10% Precision: ±3% of measurement value	
Maximum image resolution	256 x 256 pixels	
Scan speed	4ms/pixel, 10ms/pixel, 50ms/pixel	
Scan area	***Standard system*** 20cm distance (Normal area): 6.6cm x 6.6cm (Large area): 13cm x 13cm 100cm distance (Normal area): 25cm x 25cm (Large area): 50cm x 50cm	***High resolution system (moorLDI2-HIR)*** 20cm distance (Normal area): 2.5cm x 2.5cm (Large area): 5cm x 5cm 100cm distance (Normal area): 9.4cm x 9.4cm (Large area): 18.8cm x 18.8cm
Bandwidth	Lower cut-off frequency (3dB): 20/100/250Hz (Scan rate dependant) Upper cut-off frequency (0.1dB): 3/15/22.5kHz (Selectable)	
CMOS Camera	Colour, Auto Focus, 2592 x 1944 pixel resolution, 1296 x 972 (2 x binned) pixel resolution	
Operating environment	Indoor: e.g. hospital or laboratory use Temperature range: 15-30°C Humidity: 20-80% RH (excluding condensation) Atmospheric pressure: within 86.0kPa to 106.0kPa (645mmHg to 795mmHg) Lighting conditions: Normal, ambient room lighting	
Storage and transportation environment	Temperature range: 5-50°C Humidity: 20-80% RH (excluding condensation) Atmospheric pressure: 50.0-106.0kPa (375-795mmHg) Humidity: 0-80%, non-condensing	
Dimensions	Scan Head: 426x244x300mm (WxHxD) max PSU: 107x56x171mm (WxHxD) max	
Weight	Scan Head: 9.0kg PSU: 0.5kg	
Power source	AC mains, Universal switched mode, 100-230V, 50-60Hz, 50VA power consumption	

Electrical safety classification	Type of protection against electric shock – Class 1 Degree of protection against electric shock – Non-patient contact, no applied part Degree of protection against ingress of liquid – IPX0 (not protected) Degree of protection against flammable anaesthetics – equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
Medical device classification	Class IIa Active device for diagnosis under EC directive 93\42 EEC 14th June 1993 Medical Device Directive.
Laser Classification	Class 3R (per IEC 60825-1:2007)
Minimum Computer Specification	Dual core Pentium® 4 processor, 2GHz or higher compatible CPU 2GB RAM Super VGA monitor (1024 x 768 resolution or higher) 100GB of available hard drive space Operating System: Windows 7 (32/64-bit), Windows 8 (32/64-bit) 2 USB ports

Table 2

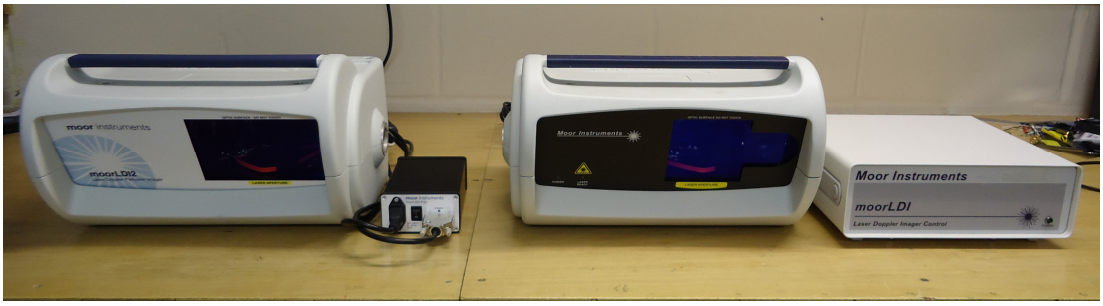
5.4 Intended Use

The moorLDI2 Laser Doppler Imager is intended for blood flow measurements in the microcirculation. It is intended to be used for clinical research applications and pre-clinical research applications. The intended use remains the same as for the predicate device.

5.5 Technological comparison to predicate device

The moorLDI2 laser Doppler imager uses the same principle of operation as the predicate device. The overall optical and mechanical design is very similar to the predicate device, but the electronic control system and associated software have been completely redesigned to resolve component obsolescence problems and to reduce the manufacturing costs.

The design of the predicate device consists of a scan head and a separate control box which contains most of the electronic control systems. In the revised design most of the electronic systems are now integrated within the scan head and the only extra component is a small external mains power supply. The external design of the scan head remains unchanged, except for revised graphics on the front panel. The following picture shows the revised design on the left and the predicate device on the right.



Although the revised design involves changes to the electronic hardware and software, it uses the same principles of operation and is intended to provide essentially the same measurement performance as the existing system. All of the major performance specifications remain unchanged.

The similarities between the systems are as follows:

- Has the same intended use.
- Uses the same operating principle.
- Has the same image resolution options.

- Has the same laser classification.
- The scan head has the same external dimensions.

The main differences between the systems are as follows:

- The revised design has all electronics, with the exception of the mains power supply, located in the scan head. Therefore it no longer requires the large external control box, just a small external PSU.
- A visible red (633nm) laser option has been added which restricts measurement depth to superficial surface blood flow.
- A high resolution option has been introduced which provides increased spatial resolution for smaller measurements sites.
- A USB camera has replaced the Firewire camera to increase reliability and reduce the build cost of the system.

The model range has been extended to include 3 variants which differ in terms of laser wavelength and image area and resolution. The model variants are related to the predicate device as shown in Table 3.

Model	**Laser** (*Wavelength*)	**Image Resolution**	**Image area**	**Comparison with predicate device**
moorLDI2-IR	Infra-red laser diode (*785nm*)	Standard	Standard	Same
moorLDI2-HIR	Infra-red laser diode (*785nm*)	High	Small	New
noorLDI2-VR	Helium Neon gas laser (*633nm*)	Standard	Standard	New

Table 3

The visible red (633nm) laser in the moorLDI2-VR system provides reduced measurement depth compared with the infrared (785nm) laser in the other two systems. The moorLDI2-HIR system is optimised to provide increased resolution for smaller measurement sites.

5.6 Performance comparison to predicate device

The moorLDI2 laser Doppler imager was tested in direct comparison to the predicate device using laboratory models and skin blood flow measurements on volunteers.

5.7 Conclusions

The moorLDI2 laser Doppler imager demonstrated that the device is as safe, as effective and performs as well as or better than the predicate device.