K083082

# 7 510(k) Summary

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| Submitter: | Moor Instruments Ltd |
| Address: | Millwey<br>Axminster, Devon<br>EX13 5HU, United Kingdom |
| Telephone: | (+44) 1297 35715 |
| Fax: | (+44) 1297 35716 |
| Contact: | Xiabing Huang |
| Contact title: | Technical Manager |
| E-mail: | xhuang@moor.co.uk |
| Date: | October 8th, 2008 |
| Model Name: | moorVMS-LDF1 Laser Doppler perfusion and temperature monitor<br>moorVMS-LDF2 Laser Doppler perfusion and temperature monitor |
| Model Number: | moorVMS-LDF1<br>moorVMS-LDF2 |
| Common Name: | Laser Doppler perfusion and temperature monitor |
| Classification Name: | 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 devices |
| Predicate Device: | DRT4 Laser Doppler perfusion and temperature monitor<br>510(k) Number K011070 |

JAN 13 2009

Moor Instruments Ltd Millwey Axminster Devon EX13 5HU UK
tel +44 (0)1297 35715 fax +44 (0)1297 35716
email sales@moor.co.uk website www.moor.co.uk
Company Registered in England No. 2209367 VAT Registration No. GB490667906

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Moor Instruments Ltd.
% Xiabing Huang
Millwey
Axminster, Devon
EX13 5HU, United Kingdom

JAN 13 2009

Re: K083082
Trade/Device Name: moorVMS-LDF1 Laser Doppler perfusion and temperature monitor
moorVMS-LDF2 Laser Doppler perfusion and temperature monitor
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 8, 2008
Received: October 16, 2008

Dear Xiabing 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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

Enclosure

# 5 Indications for Use Statement

510(k) Number: K 083082

Device name: moorVMS-LDF1 Laser Doppler perfusion and temperature monitor
moorVMS-LDF2 Laser Doppler perfusion and temperature monitor

Indications for use:

The moorVMS-LDF1 and moorVMSLDF2 laser Doppler perfusion and temperature monitors are intended for simultaneous measurement of tissue temperature and blood flow in the microcirculation. The devices are intended for clinical research use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

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

**510(k) Number** K083082