

APR 30 1998

K 980383

Premarket Notification 510(k) Summary

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Date:	15/01/1998

Classification Name:	Not Known
Common/Usual Name:	Laser Doppler Perfusion Imager
Trade/Proprietary Name:	moorLDI Laser Doppler Imager
Establishment Registration No:	8043564
Classification:	Regulatory Class II
Performance Standard:	The equipment conforms to the provisions of US 21 CFR 1040.10 and 1040.11 as a Class IIIa Medical Laser Product.
Reason for Submission:	New Device
Predicate Devices:	PIM 1.0 Laser Doppler Perfusion Imager 510(k) Number - K920844 Moor Laser Blood Flow Monitor MBF3D 510(k) Number - K905232

Description of the Device

The moorLDI laser Doppler imager is a device for imaging blood flow in the microcirculation of surface tissue e.g. blood flow in skin. It uses the established laser Doppler technique to quantify movement of blood cells beneath the skin surface. Unlike existing laser Doppler monitors, which use optical fibre probes at fixed tissue sites, moorLDI scans a low power laser beam in a raster pattern over the skin surface to build up a colour coded image of blood flow.

A beam of light from a low power HeNe red laser is directed by a moving mirror which is driven by the DC servo motors to execute a raster pattern across the tissue surface. The incident light is scattered by static tissue and by moving blood. The Doppler frequency shifted light from moving blood and non-shifted light from tissue is then directed by the same moving mirror (and focusing lenses) onto two photodiodes. Light 'beats' at the detectors due to constructive and destructive mixing of the light. These intensity fluctuation are then processed in suitable electronic circuits to give parameters of flux (proportional to tissue blood flow) and conc (proportional to the concentration of moving blood cells). The outputs of the Doppler signal processor and a DC signal (the light intensity) are sent to the computer (PC) via an opto isolated RS232 serial port, so an intensity photo image and a colour-coded blood flow image can be displayed and processed by the computer.

The moorLDI consists of a control box, scanner head and optional bench top or a mobile stand. The system interfaces with the PC via an opto isolated RS232 serial port at a baud rate of 19200. The moorLDI control box contains a power supply unit and all main electronic circuit board. The optical and mechanical components are mounted on the base plate of the scanner head. The control signals for the mirror, shutter, laser power attenuator, etc. are provided by the control box via a 37 way cable. The laser Doppler shifted signals detected by the photo detector board, which is mounted on the base plate of the scanner head, are sent to the control box via a 9 way analogue cable.

Intended Use

The moorLDI Laser Doppler Imager is intended for blood flow studies in a wide range of clinical research applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anaesthetics.

Technological Characteristics

- **moorLDI Compared with PIM 1.0 Laser Doppler Imager**

The moorLDI and PIM 1.0 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 difference is the beam scanning method. The PIM 1.0 scans a laser beam in a step mode, i.e. the laser beam is halted for about 50ms at each measurement site to allow the stepper motors time to settle and then the measurement is taken. The moorLDI uses a continuous mode of scanning. For each line scan the laser beam is scanned at a constant speed across the tissue surface with measurements made at regular intervals along the scan line. This mode of scanning, in comparison to stopping the beam for each measurement, eliminates the need for a settling time and enables relatively short imaging times to be achieved. For a 256×256 pixel image, the moorLDI takes under 5 minutes when the 4ms/pixel scan speed is selected. This is approximately the same time for a 64×64 pixel image recorded with the PIM 1.0 imager. The moorLDI provides optional scan speeds of 4ms/pixel, 10ms/pixel or 50ms/pixel and implements a high pass filter with different high pass cut-off frequencies for different speeds to reduce movement artefact introduced by continuous image scanning. Measurements with a moorLDI have demonstrated that: 1) the high pass filter with higher cut-off frequency (e.g. 250Hz for 4ms/pixle scan speed) effectively removes the movement artefact with small loss of low flow information. 2) A slow scan speed (e.g. 50ms/pixel) can be used to improve the signal quality when looking at a low flow region. At this scan speed a high pass filter with a cut-off frequency of 20Hz is used. The PIM 1.0 imager has a high pass filter of 20Hz and a low pass filter of 10khz. The moorLDI has low pass frequency options of 3KHz, 15KHz and 22KHz.

The other main difference between the two imagers is the light collection method. The PIM 1.0 uses a single photodetector for collecting the scattered light from the tissue surface so a relatively small amount of light collected. This is the main reason that the PIM 1.0 can only work at a distance range of 15cm to 20cm from the system to patient tissue surface and requires low light conditions. In contrast to the PIM 1.0, the moorLDI uses a 100mm diameter mirror to direct the beam to the tissue surface and reflect laser light scattered from this surface to two large area convex lenses which focus the collected light to two photodetectors; therefore a relatively large amount of scattered light can be collected with a consequent improvement in the signal to noise ratio. Use of two photodetectors also enables the moorLDI to implement a differential amplifier circuit to reduce common mode noise such as laser noise, ambient light and mains interference. As a result, the moorLDI achieves a working distance range of 20cm to 100cm and a tissue surface scan area upto 50cm × 50cm. In addition, a pair of narrow pass band optical filters are fitted in the front of the photodetectors so the moorLDI can work under ambient light conditions, which makes its operation convenient for the user. The PIM 1.0 which does not have optic filters has to be operated in a darkened room.

- **moorLDI Compared with the Moor Instruments MBF3D Laser Doppler Monitor**

The basic principle of measurement and the technical features of the moorLDI and MBF3D monitor are the same in that they both utilise the Doppler broadening of a low power laser beam to record tissue perfusion, and they both use the same analogue circuit design for laser Doppler signal processing. The MBF3D uses optical fibres to transmit laser light to a tissue site and collect light scattered from the tissue. An optical probe is placed in contact with the skin to provide a real-time continuous blood flow measurement at a fixed site. The moorLDI provides a two dimensional colour coded image of blood flow from a scanned tissue area, and with a fixed beam position provides a real-time continuous blood flow measurement at a fixed point. Since the laser beam is directed to the tissue surface remotely, there is no contact between the tissue surface and the moorLDI during measurements.

Performance Data

In order to evaluate the performance of the moorLDI and determine its substantial equivalence to the PIM 1.0 laser Doppler perfusion imager and the MBF3D laser Doppler monitor, a set of tests has been carried out. A brief discussion of these testes are given below.

- **Flow Model**

A flow simulator was constructed to evaluate the predicted linear relationship between measured perfusion values from the moorLDI and flow rates. The flow model consisted of five rows of the silicone rubber tubing, with inner diameter of 0.76mm, laid side by

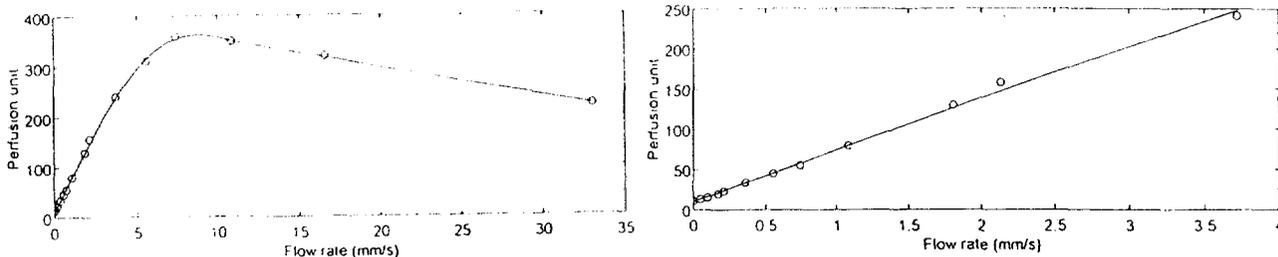


Figure 4-1. moorLDI Flux Output vs Flow Rate
 (Measurement: single point, Bandwidth: 20Hz to 15KHz)

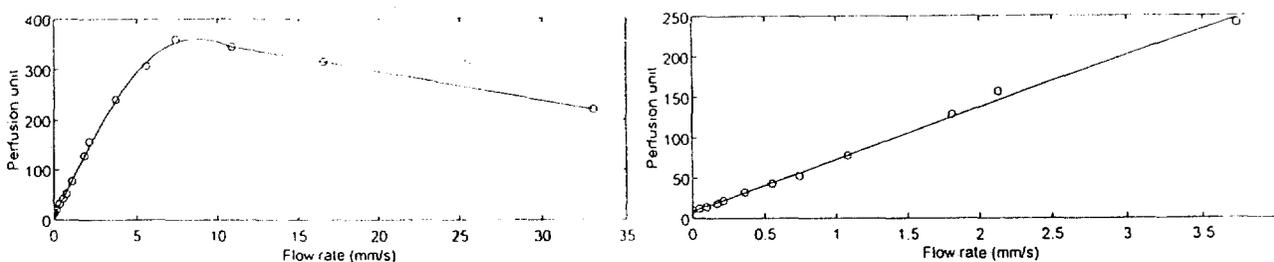


Figure 4-2. moorLDI Flux Output vs Flow Rate
 (Measurement: single point, Bandwidth: 250Hz to 15KHz)

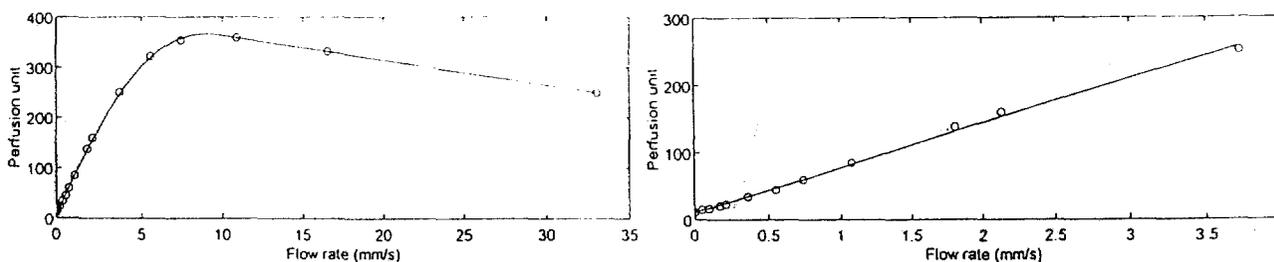


Figure 4-3. moorLDI Flux Output vs Flow Rate
 (Measurement: image scan, Scan Speed: 50ms/pixel, Bandwidth: 20Hz to 15KHz)

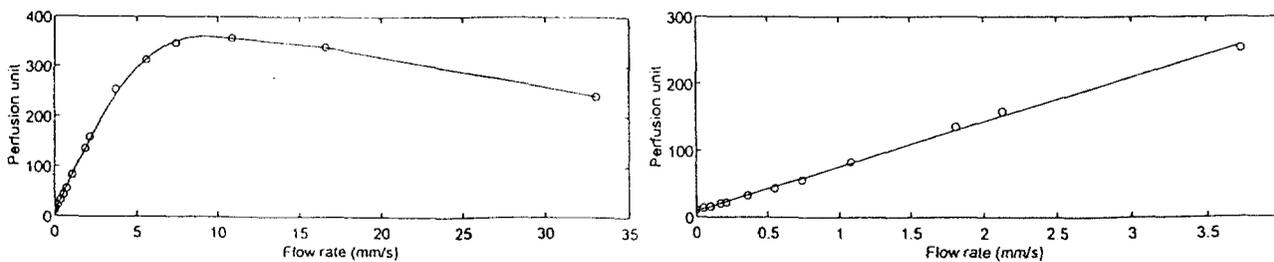


Figure 4-4. moorLDI Flux Output vs Flow Rate
 (Measurement: image scan, Scan Speed: 4ms/pixel, Bandwidth: 250Hz to 15KHz)

side over an aluminium reflective background. A translucent plastic cover was placed over the top of the lengths of tube to simulate the diffusing effect of skin tissue on incident laser light. The motility standard was diluted down to 0.1% solution with purified water and pumped through the tube by an infusion pump to simulate the blood flow.

For each rate of flow, two types of measurements were performed, i.e. 1) non-scan mode at a fixed beam position with lower cut-off frequencies of 20Hz, 100Hz and 250Hz, 2) imaging the whole flow model at two scan speeds, 4ms/pixel and 50ms/pixel.

The results (Figures 4-1 to 4-4) show that a linear relationship between the flux outputs and the flow rates has been established for different lower cut-off frequencies and different scan speeds. The use of the higher cut-off frequency (250Hz) for the high pass filter effectively reduces the movement artefact introduced by the fast image scanning with small loss of low flow information.

- **Assessment of Movement Artefact**

This test was designed to assess the effect of continuous beam movement on flux measurement which is one of the technical differences between the moorLDI and PIM 1.0.

The measurements were taken forearm using a stationary beam and scan speed of 50ms/pixel, 10ms/pixel and 4ms/pixel.

Scan Speed	Bandwidth	Forearm
Stationary	20Hz-15KHz	25 ± 4.1
50ms/pixel	20Hz-15KHz	24 ± 4.5
10ms/pixel	100Hz-15KHz	24 ± 6.4
4ms/pixel	250Hz-15KHz	25 ± 7.7

The results indicate that compared with the stationary measurement, comparable flux values can be obtained even at a 4ms/pixel scan speed with 250Hz lower cut-off frequency. The continuous beam movement is not considered to compromise the effectiveness of the moorLDI used as a tool for blood flow measurement. In fact for clinical research reduced scan times are a significant advantage.

- **Single Point Measurements**

In addition to laser Doppler image scanning, the moorLDI provides a single point measurement function, enabling monitoring of the blood flow signal with time at a fixed position. This is comparable to the blood flow measurement made with a laser Doppler monitor such as the Moor Instrument MBF3D. For comparison, both the MBF3D and moorLDI were used to monitor Flux and Conc signals at the finger tip. A pressure cuff

was used to partially occlude and then release the blood flow to see the changes in the laser Doppler signals monitored by the MBF3D and moorLDI. The signals recorded by the MBF3D monitor and the moorLDI running in single point mode illustrates their equivalence in terms of blood flow measurement. The advantage of the moorLDI for this type of measurement is that there is no direct contact with the tissue surface other than the laser beam, the beam can be directed remotely to any position within the image area, and as there are no optic fibres noise associated with fibre movement is eliminated.

- **Image Scanning**

To compare the performances of the moorLDI with that of the PIM 1.0 and to illustrate the high resolution image capability of the moorLDI, a series of image scans were performed.

Images of blood flow in the dorsum of the hand were recorded using the moorLDI at two resolutions (64 x 64 pixels and 256 x 256 pixels) and the PIM 1.0 at its maximum resolution of 64 x 64 pixels. All three laser Doppler images show similar blood flow distributions (Figures 4-9, 4-10 and 4-11). The 256 x 256 pixels photo and laser Doppler images recorded with the moorLDI has more detailed information compared with the PIM 1.0 64 x 64 image recorded in a similar overall scan time of approximately 5 minutes. The moorLDI 64 x 64 pixels image is similar to the PIM 1.0 image yet can be scanned in approximately 40 seconds.

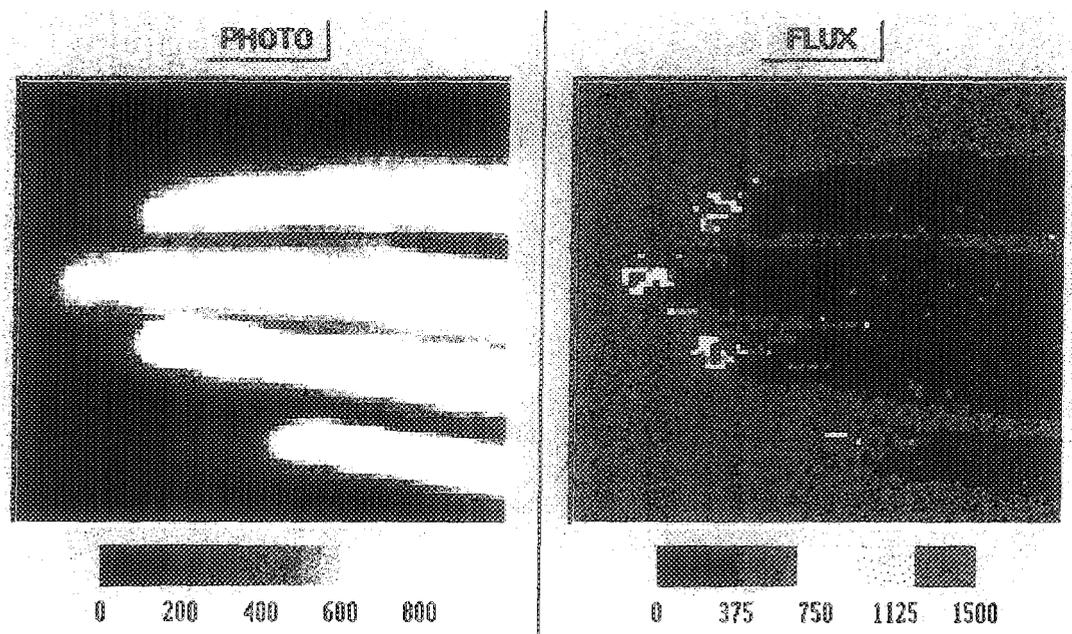


Figure 4-9. Photo and Laser Doppler Images Obtained by the moorLDI
Scan Mode: continuous at scan speed of 4ms/pixels
Resolutions: 64 x 64 pixels
Time Taken: approx. 45 seconds

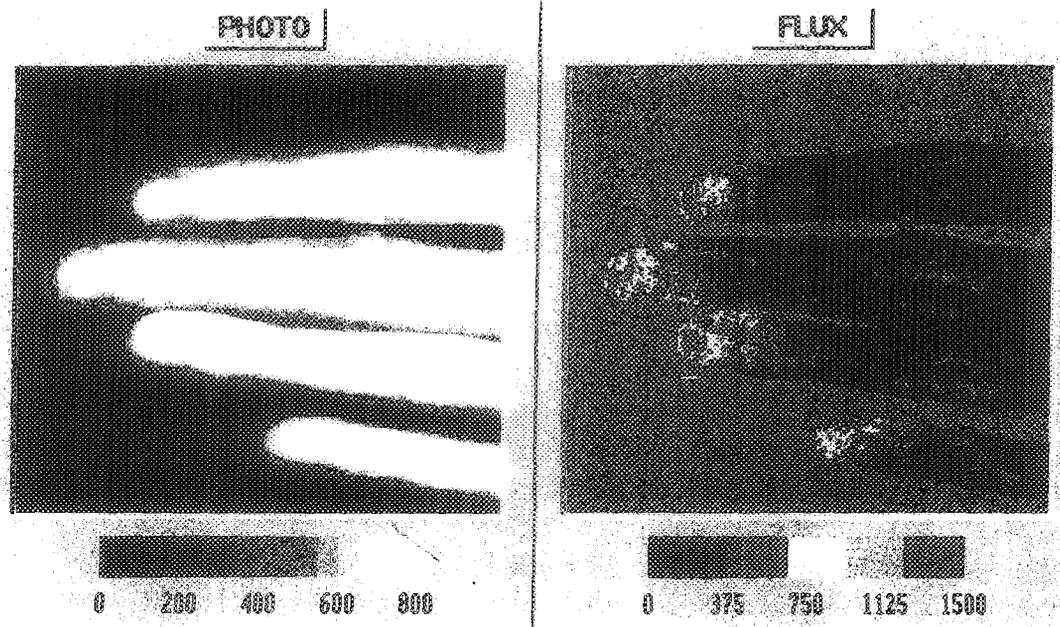


Figure 4-10. Photo and Laser Doppler Images Obtained by the moorLDI
 Scan Mode: continuous at scan speed of 4ms/pixels
 Resolutions: 256 x 256 pixels
 Time Taken: approx. 4 minutes and 45 seconds

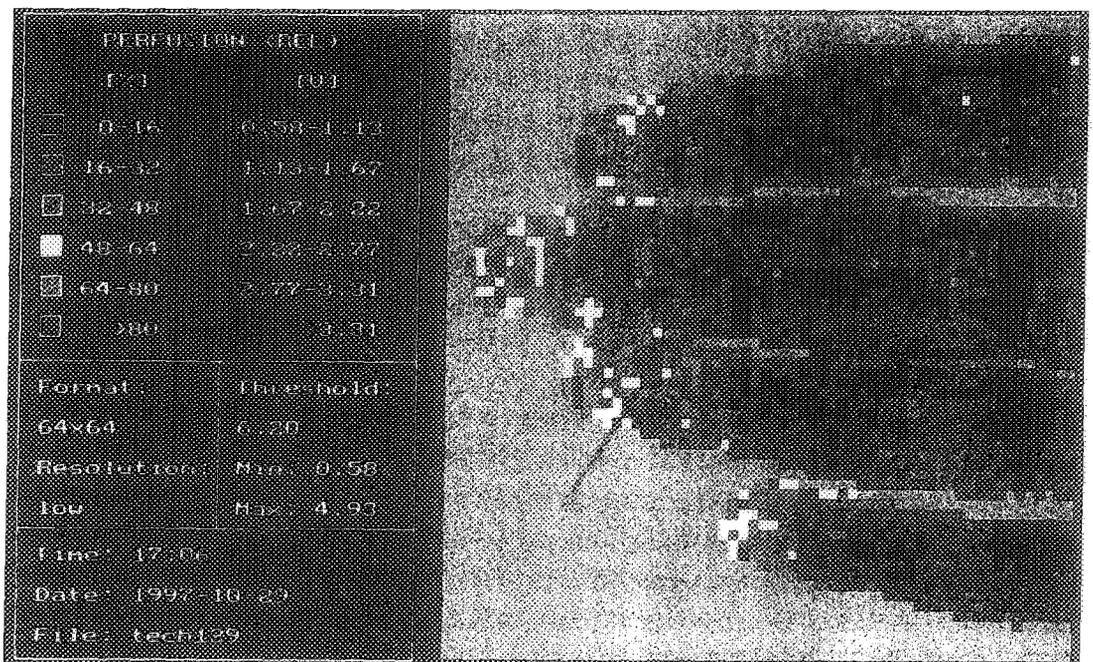


Figure 4-11. Laser Doppler Images Obtained by the PIM 1.0
 Scan Mode: step, 50ms for each measurement
 Resolutions: 64 x 64 pixels
 Time Taken: approx. 4 minutes

The moorLDI has a photodetection system with a large effective light collecting area. Because of this it has a working distance of upto 100cm between the scan head and the tissue surface and can scan over areas as large as 50cm x 50cm. This compares with the 15cm x 15cm of the PIM 1.0.

- **Compared with Microsphere Technique**

The radiolabelled microsphere technique is a well-established technique for quantitative measurements of blood flow. Experiments were performed in 12 adult male New Zealand rabbits to evaluate the moorLDI for measuring blood flow in the rabbit knee joint capsule. The femoral artery of one hindlimb was cannulated both proximally and distally, and the circulation to the hindlimb controlled via a pump (Gilson minipuls). During the experiment, two pump speeds were selected: a low speed (2.8 ml/min) and a high speed (11.0 ml/min). The microsphere labels and the pump speeds were randomly varied between experiments, and for each pump speed, image scans at three different scan rates (4ms/pixel, 10ms/pixel and 50ms/pixel) were performed. Therefore, a total of 72 images have been obtained.

The comparison of the moorLDI and microsphere measurement techniques yielded highly significant correlations (correlation coefficient $r = 0.9$), which is higher than a significant correlation of $r = 0.76$ obtained by using the PIM 1.0 in similar experiments. Comparison of the three scan speeds demonstrated acceptable agreement without significant bias between measurements, suggesting that the inevitable narrowing of the bandwidth at the fastest scan speed (4ms/pixel) does not cause significant deterioration of the signal. These results validate the use of LDI for the assessment of joint capsule perfusion.

Ref: J. Lockhart, W. Ferrell and W. Angerson. *Laser Doppler Perfusion Imaging of Synovial Tissues Using Red and Near Infra-Red Lasers*. Int. J Microcirc, 1997; 17:130-137. (Appendix B3)

- **Compared with PIM 1.0: Measurement in Knee Ligaments of Adult Rabbits**

The purpose of this study is to compare two different laser Doppler imaging technologies for measuring blood flow in hypoaemic (low flow) tissues, one is the PIM 1.0 using step scanning method and the other is the moorLDI using continuous scanning method. Experiments were performed on 9 female, one year old, New Zealand White rabbits. Normal and knee-injured rabbits were used. Knee injuries consisted of transection of the intra-articular anterior cruciate ligament (ACL) of the right knee according to a standardised protocol. LDI measurements were made in the exposed medial collateral ligament (MCL) at several intervals after ACL transection. All LDI measurements for both imagers were obtained sequentially from exposed MCLs.

The comparison between the mean LDI outputs from the PIM 1.0 and the moorLDI shows that the data points were significantly correlated ($r = 0.999$). The results suggest that the effects of a continuous moving laser beam on the perfusion measurement is not statistically significant for the flows present in these MCLs. The flows measured in this experiment were not significantly affected by the band pass and faster scanning technique of the moorLDI.

Ref: K. Forrester, M. Doschak and R. Bray. *In Vivo Comparison of Scanning Technique and Wavelength in Laser Doppler Perfusion Imaging: Measurement in Knee Ligaments of Adult Rabbits*. Medical & Biological Engineering & Computing 1997, Nov. (Appendix B4)

Safety and Certification Standards

The moorLDI has been fully tested by BSI (British Standard Institute) and has been found to comply with following standards:-

IEC 601-1:1988 including Amendment 1, 1991 and Amendment 2, 1995/
EN 60601-1:1990 including Amendments A1, A11, A12 and A2
excluding IEC 601-1-4 reference in Sub-clause 52.1,
IEC 601-2-22:1995/BS EN 60601-2-22:1996,
BS EN 60825-1:1994/IEC 825-1:1993
UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
CSA Standards C22.2
No 0 - General Requirements, Canadian Electrical Code, Part II
No 601.1-M90: Medical Electrical Equipment, Part 1: General
Requirements for Safety
No 601.1-1S1-94: Supplement No 1-94 to C22.2
No 601.1-M94
No 601.2.22-94: Medical Electrical Equipment, Part 2.22: Specification for
Diagnostic and Therapeutic Laser Equipment

The classification of the moorLDI is as follows:

Type of protection against electric shock:	Class I
Degree of protection against electric shock:	Type B
Degree of mobility:	Portable
Laser class:	3B
Wavelength:	633nm
Maximum accessible power:	He-Ne laser 2.0mW

BSI test report is attached in Appendix D1
CSA test report is attached in Appendix D2

Conclusions

From the above performance data, it can be seen that the moorLDI provides a non-invasive and non-contact technique for blood flow imaging and monitoring. The main conclusion which can be drawn from the above tests is that the moorLDI is substantial equivalence to the MBF3D and PIM 1.0 in terms of effectiveness and safety.

Compared with the MBF3D laser Doppler monitor, the features of non-contact measurement and blood flow imaging suggest that the moorLDI is a more effective device for tissue blood flow measurement and safer because it is non-contact .

Compared with the PIM 1.0 laser Doppler perfusion imager, the features of wide working distance range, large image size, image resolution up to 256×256 pixels and fast image scan speed up to 4ms/pixel significantly enhance the effectiveness of the moorLDI used for blood flow measurements and extend the application of the laser Doppler imaging technique in the blood flow studies.



APR 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. David Boggett
Managing Director
Moor Instruments Limited
Medical and Opto-Electronic Instrumentation
Millwey Axminster
Devon EX13 5HU, England

Re: K980383
Trade Name: moorLDI Laser Doppler Imager
Regulatory Class: II
Product Code: GEX
Dated: January 19, 1998
Received: February 2, 1998

Dear Dr. Boggett:

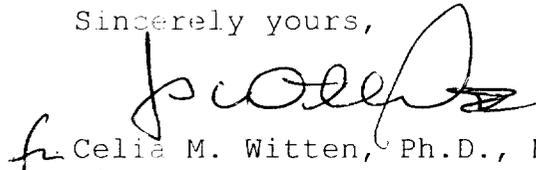
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Dr. Boggett

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K980383

DEVICE NAME: moorLDI Laser Doppler Imager

INDICATIONS FOR USE:

The moorLDI Laser Doppler Imager is intended for studies of blood flow in the microcirculation, e.g. blood flow in the small blood vessels of the skin. It is suitable for a wide range of clinical research applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anaesthetics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980383

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)