JUL 9 1998

K980538

APPENDIX F

510(k) SUMMARY
TRANSMEDICA INTERNATIONAL, INC.
LASER LANCET® LB100

This 510(k) summary of safety and effectiveness for the Laser Lancet® LB100 is submitted in accordance with the requirements of the SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	TRANSMEDICA INTERNATIONAL, INC.
Address:	323 Central Street Suite 1100 Little Rock, AR 72201
Contact Person:	Kevin Marchitto, Ph.D. Vice President of Technology and Business Development
Telephone:	502-376-3938 502-376-3969 (Fax)
Preparation Date:	February 9, 1998
Device Trade Name:	Laser Lancet® LB100
Common Name:	Er:YAG laser
Classification Name:	Surgical Laser (see: 21 CFR 878.4810). Product Code: GEX.
Legally marketed predicate device:	Steel Lancet (as described in K931258), Laser Lancet (as described in K955653)
Device Description:	The Laser Lancet® LB100 is a portable Er:YAG laser. The beam is focused within the unit and exits through a tube placed in the aperture allowing the focused beam to strike the finger of a patient placed against the unit's tip and perforate the skin. The resulting blood sample is used for clinical chemistry screening purposes.
Intended Use:	The Laser Lancet® is intended for use for the perforation of skin to draw capillary blood for screening purposes.

Performance Data: Clinical data from two studies demonstrated that the energy output of the Laser Lancet® LB100 is effective in perforating the skin in order to obtain capillary blood for screening tests.

The results of one clinical study demonstrated that the clinical values of electrolytes and lipids were the same whether the capillary blood was obtained after use of the Laser Lancet® LB100 or by a steel lancet.

The results of the second study demonstrated that the perforation sites, including multiple perforations on the same finger of diabetic patients, were healed within 48 hours after use of the Laser Lancet®.

CONCLUSIONS: Based on the foregoing and other information in this application, TransMedica International, Inc. believes that the

a. Laser Lancet® LB100, with the specifications as described in this notification and under conditions of proposed use, is substantially equivalent to the Laser Lancet® described in K955653,

b. clinical data provides reasonable assurance that the Laser Lancet® LB100 does not pose undue risks to patients, even after multiple perforations, and

c. clinical data provide reasonable assurance that equivalent results are obtained for lipids and electrolytes (in addition to the colorimetric analyses approved with the initial 510(k)) whether the capillary blood is collected after perforation with the Laser Lancet® LB100 or with a steel lancet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 1998

Kevin Marchitto, Ph.D.
Transmedica International, Inc.
Vice President, Technology and Business Development
323 Center Street, Suite 1100
Little Rock, Arkansas 72201

Re: K980538
Trade Name: Laser Lancet LB100
Regulatory Class: II
Product Code: GEX
Dated: May 11, 1998
Received: May 12, 1998

Dear Dr. Marchitto:

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 (Premarket 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.

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

APPENDIX B

INDICATIONS FOR USE

Application Number (if known): K980538

Device Name: Laser Lancet® LB100

Indications For Use:

The Laser Lancet® is intended for use for the perforation of skin to draw capillary blood for screening purposes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980538