PELIKAN ● TECHNOLOGIES

K024170

510(k) Summary
L1 System
Pelikan Technologies, Corp.

APR 1 4 2003

Prepared December 6, 2002

Product Name: L1 System

Manufacturer: Pelikan Technologies, Corp.

Generic Name: Blood lancet

Classification Name: Manual surgical device for general use; blood lancet (Class I); Classification code: FMK; 21 CFR 878.4800

Contact Person: Jack S. Green, CQM
Quality Assurance Manager
Pelikan Technologies, Corp.
1072 East Meadow Circle
Palo Alto, California 94303

A. Legally Marketed Predicate Device
The L1 System is substantially equivalent to the SoftTouch Lancet Device manufactured by Boehringer Mannheim Corporation (K931258).

B. Device Description
Handheld, battery powered electronic lancing system for home use by individuals and caregivers to obtain blood samples.

C. Intended Use
The L1 System is an automatic blood lancet device used to obtain a capillary blood sample.

D. Substantial Equivalence
The L1 system is substantially equivalent to the intended use and technological characteristics of the Soft Touch predicate device.

E. Performance Data
Testing performed under the Design Control Process verified that the L1 System performed according to specifications and is in compliance with all applicable performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2003

Mr. Jack S. Green, CQM
Quality Assurance Manager
Pelikan Technologies Corporation
1072 East Meadow Circle
Palo Alto, California 94303

Re: K024170
Trade/Device Name: L1 System
Regulation Number: 21 CFR 878.4800
Regulation Names: Manual surgical instrument for general use
Regulatory Class: I
Product Codes: FMK
Dated: March 4, 2003
Received: April 1, 2003

Dear Mr. Green:

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 Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

PELIKAN ● TECHNOLOGIES

Indications for Use Statement

510(k) Number (if known): K024170

Device Name: L1 System

Indications For Use:
The L1 System is an automatic blood lancet device used to obtain a capillary blood sample.

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

_____Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use _____
(Per 21CFR 801)

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for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024170