K973012

NOV - 5 1997

SECTION 10: SUMMARY OF SAFETY AND EFFECTIVENESS

10.1 SUBMITTER INFORMATION

Company Name:	MDC Research Ltd.
Company Address:	2810 Bunsen Avenue Ventura, California 93003
Telephone:	(805) 339-0375
Contact Person:	James M. Donegan Chief Executive Officer Chairman

Date Prepared:	August 11, 1997

10.2 DEVICE IDENTIFICATION

Common/Usual Name:	Blood Collection Needle System
Proprietary Name:	Safe Step Safety Blood Collection Needle System

10.3 IDENTIFICATION OF PREDICATE DEVICE

The Safe Step Safety Blood Collection Needle System, with its components, is substantially equivalent to the following previously cleared and currently marketed device:

Bio-Plexus, Inc. Punctur-Guard Blood Collection Needle System, 510(k) #K895024, cleared on September 21, 1990.

10.4 DEVICE DESCRIPTION

The Safe Step Safety Blood Collection Needle System consists of four separate components: a blood collection needle assembly; an evacuated tube adapter; a front protective cap; and a rear protective cap.

The Safe Step Safety Blood Collection Needle System is a standard Blood Collection Needle System with the additional feature of a retractable needle. The needle safety mechanism can be activated by lifting the thumb pad (located on the rear piece of the tube adapter) upwards and forward, relative to the two finger tabs on the tube adapter front piece, after removing the last blood sample tube.

After needle retraction, the device is disposed of according to routine procedure in a sharps container.

10.5 SUBSTANTIAL EQUIVALENCE

The Safe Step Safety Blood Collection Needle System is substantially equivalent to other Blood Collection Needle Systems currently in commercial distribution by BioPlexus, Inc. in terms of the intended use as a Blood Collection Needle System,

providing vein access for the purpose of obtaining blood specimens using an evacuated blood collection tube, and the incorporation of a safety feature to cover the needle after use.

The technical characteristics are similar to those of the predicate device. Differences that exist between these systems relating to physical appearance and materials do not affect the relative safety or effectiveness of the devices.

10.6 INTENDED USE

A properly placed MDC Safe Step Safety Blood Collection Needle System incorporates a retractable needle safety mechanism to minimize needle stick injuries when used to access a vein to obtain blood samples.

10.7 TECHNOLOGICAL CHARACTERISTICS

The Safe Step Safety Blood Collection Needle System has the same technological characteristics as the Punctur-Guard Blood Collection Needle System. Both devices provide vein access to collect blood specimens and include a user activated feature to cover the needle after use.

10.8 PERFORMANCE DATA

Performance data indicate that the Safe Step Safety Blood Collection Needle System meets the functional requirements and specifications of this device.

16.9 510(K) CHECKLIST

This notification contains all of the information required by 21 CFR 807.87. A.

completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol L. Patterson
Official Correspondent
MDC Research Ltd.
2810 Bunsen Avenue
Ventura, California 93003

NOV - 5 1997

Re: K973012
Trade Name: Safe Step™ Blood Collection Needle System
Regulatory Class: II
Product Code: FMI
Dated: August 11, 1997
Received: August 13, 1997

Dear Ms. Patterson:

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) 594-4618. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K973027

Device Name: MDC Safe Step Safety Blood Collection Needle System

Indications For Use:

A properly placed MDC Safe Step Safety Blood Collection Needle System incorporates a retractable needle safety mechanism to minimize needle stick injuries when used to access a vein to obtain blood samples.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cucenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973012

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)