K022959

FEB 0 5 2003

SECTION 16: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

16.1 SUBMITTER INFORMATION

a.	Company Name:	MDC Research Ltd.
b.	Company Address:	2810 Bunsen Avenue Ventura, CA 93003
c.	Company Phone: Company Facsimile:	(805) 339-0375 (805) 339-9751
d.	Contact Person:	David Dowsett Executive V.P. and C.O.O.
e.	Date Summary Prepared:	December 11, 2002

16.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	SafeStep™ Safety Dental Cartridge Injector
b.	Classification Name:	Cartridge Syringe 21 CFR 872.6770

16.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Specialties Septodont	Safety Plus Dental Needle System	K913573	11/07/91

16.4 DEVICE DESCRIPTION

The SafeStep™ Safety Dental Cartridge Syringe consists of a single-use, disposable aspirating syringe-type injector with a separate re-usable plunger assembly indicated for the use in delivering dental anesthetics. The SafeStep™ Safety Dental Cartridge Syringe incorporates a needle safety mechanism that can be activated with one hand.

16.5 SUBSTANTIAL EQUIVALENCE

The SafeStep™ Safety Dental Cartridge Injector is substantially equivalent to the Septodont Safety Plus Dental Needle Injection System in terms of function, materials, and intended use. In a simulated use clinical study, the SafeStep™ Safety Dental Cartridge Injector was found to perform equivalently to the predicate device.

16.6 INTENDED USE

The SafeStep™ Safety Dental Cartridge Injector is a sterile, single use disposable injector barrel assembly and a reusable plunger assembly that is indicated for use with pre-filled, 1.8mL, anesthetic cartridges and existing screw-on dental needles for injection of anesthetic solution in oral tissues. The SafeStep™ Safety Dental Cartridge Injector aids in the prevention of needle stick injuries. The SafeStep™ Safety Dental Cartridge Injector incorporates a needle retraction and re-advancing mechanism which may be operating with one hand.

16.7 TECHNOLOGICAL CHARACTERISTICS

The SafeStep™ Safety Dental Cartridge Injector is equivalent to the Septodont Safety Plus in terms of materials, function and intended use. Both devices are constructed of a single use, disposable injector barrel component and a reusable plunger assembly. Both devices utilize pre-filled 1.8 mL dental anesthetic cartridges and standard screw-on dental needles.

16.8 NON-CLINICAL STUDIES

Performance testing of the SafeStep™ Safety Dental Cartridge Injector included thermal stress, functional attribute, injection force, compression/tension loading before and after retraction, release force, leakage/splatter and aspiration testing. The results of the performance evaluations of the SafeStep™ Safety Dental Cartridge Injector were found to be acceptable in all test cases.

The materials of the SafeStep™ Safety Dental Cartridge Injector were tested for biocompatibility in accordance with ISO standards. The results of the biocompatibility tests, including cytotoxicity, sensitization and acute intracutaneous reactivity, were found to be acceptable.

The SafeStep™ Safety Dental Cartridge Injector is sterilized by gamma irradiation using a dosage of 25 kGy. Sterilization validation is to be performed on the final form-fill-seal production package in accordance with ANSI/AAMI/ISO 1137-1999 using Method 1 validation. MDC Research certifies that the SafeStep™ Safety Dental Cartridge Injector will pass ANSI/AAMI/ISO 11137-1994, Method 1 validation prior to marketing of the device.

16.9 CLINICAL STUDIES

MDC Research Ltd. conducted a simulated use clinical study to evaluate the safety and effectiveness of the MDC SafeStep™ Safety Dental Cartridge Injector (SDCI), for use in the injection of dental anesthetic medication into a patient. The primary research hypothesis being tested is that the use of the MDC SDCI for injection of dental anesthetic medication causes zero prevalence of sharp injuries, or failures of the safety protection feature of the device that could reasonably lead to a sharps injury. The simulated use clinical study evaluated the MDC SafeStep™ Safety Dental Cartridge Injector in comparison to the Septodont Safety Plus predicate device.

The results of the simulated use study demonstrated that the MDC SDCI is equivalent to the Septodont Safety Plus predicate device in terms of performance and evaluator preference. Further, there were no adverse events reported (i.e., sharps injuries) and no failures of the protection feature of the device that could reasonably lead to a sharps injury.

16.10 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission. Performance testing, non-clinical and clinical evaluations of the SafeStep™ Safety Dental Cartridge Injector show that the device performs as intended. Comparison the SafeStep™ Safety Dental Cartridge Injector to the predicate devices show that the device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2003

MDC Research Limited
C/O Ms. Carol Patterson
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 92630

Re: K022959
Trade/Device Name: SafeStep™ Safety Dental Cartridge Injector
Regulation Number: 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: December 11, 2002
Received: December 13, 2002

Dear Ms. Patterson:

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) 594-4613. 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 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022959

INDICATION FOR USE

510(k) Number: K022959

Device Name: SafeStep™ Safety Dental Cartridge Injector

Indications for Use: The SafeStep™ Safety Dental Cartridge Injector is a sterile, single use disposable injector barrel assembly and a reusable plunger assembly that is indicated for use with pre-filled, 1.8mL, anesthetic cartridges and existing screw-on dental needles for injection of anesthetic solution in oral tissues.

The SafeStep™ Safety Dental Cartridge Injector aids in the prevention of needle stick injuries.

The SafeStep™ Safety Dental Cartridge Injector incorporates a needle retraction and re-advancing mechanism which may be operated with one hand.

(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)

Ken Mulley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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