

NOV 18 1998

510(k) PREMARKET NOTIFICATION  
NMT Safety Syringe

K982431

## APPENDIX 8: NMT SAFETY SYRINGE RELEASEABLE 510(k) SUMMARY

**NMT Safety Syringe**  
**Releaseable 510(k) Summary.**

This summary regarding 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1) Date of Summary: July 10th, 1998.

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2)

Device Name: NMT Safety Syringe  
Common Name: Safety Syringe  
Classification name: Piston Syringe

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3)

Substantially Equivalent Device: VanishPoint™ Syringe  
510(k) Number: K946219

4)

**General**

The NMT Safety Syringe is a standard piston syringe with integral needle. The syringe incorporates automatic retraction technology that enables contaminated needles to be withdrawn, safely inside the body of the syringe when the syringe plunger is fully depressed.

The NMT Safety Syringe is available as a 3cc syringe with 20 to 25g needles.

5)

The function of the NMT Safety Syringe is to provide a safe and reliable method of injecting medication into a patient that also protects the user from potential needlesticks.

The NMT Safety Syringe functions as a conventional hypodermic syringe except for its ability to retract the contaminated needle inside the syringe immediately after the completion of the patient injection. Complete delivery of the syringe contents activates the retraction mechanism. Because the contaminated needle is automatically withdrawn into the syringe barrel, the syringe user is protected from

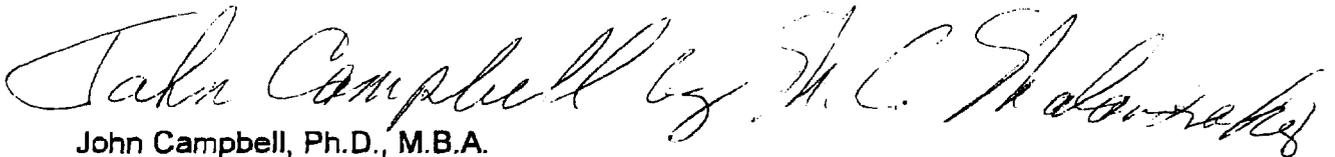
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accidental needlesticks. These accidental needlesticks would occur between removing the needle from the patient and disposing of the syringe in a sharps disposable container.

6)

The NMT Safety Syringe is substantially equivalent to the previously marketed VanishPoint™ syringe. Technologically, both devices are standard piston syringes which utilize springs to retract the needle when the plunger is fully depressed. Both devices are designed for one-handed operation and have the same intended use. Bench testing has been conducted to examine the key operations associated with the use of both devices. This has included evaluation of the dead space in the device, the graduated capacity, the forces involved with the operation of the retraction mechanism and the pressure rating of the devices under worst case static loading. In all cases the NMT Safety Syringe was either equivalent to, or exceeded the performance of the VanishPoint™ syringe.



John Campbell, Ph.D., M.B.A.  
Chief Executive Officer

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

New Medical Technology Limited  
C/O John Campbell, Ph.D., M.B.A.  
Chief Executive Officer  
New Medical Technology  
1500 West Oak street, Suite 200  
P.O. Box 317  
Zionsville, Indiana 46077

Re: K982431  
Trade Name: NMT Safety Syringe  
Regulatory Class: II  
Product Code: MEG  
Dated: October 5, 1998  
Received: October 7, 1998

Dear Dr. Campbell:

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.

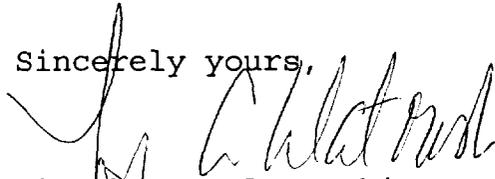
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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. Campbell

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) 594-4692. 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

510(k) PREMARKET NOTIFICATION  
NMT Safety Syringe  
APPENDIX 10: INDICATIONS FOR USE SHEET

INDICATION FOR USE

510(k) Number (if known): Unknown

Device Name: NMT Safety Syringe

Indications for Use For subcutaneous and intramuscular use.

The function of the NMT Safety Syringe is to provide a safe and reliable method of injecting medication into a patient that also protects the user from potential needlesticks.

The NMT Safety Syringe functions as a conventional hypodermic syringe except for its ability to retract the contaminated needle inside the syringe immediately after the completion of the patient injection. Complete delivery of the syringe contents activates the retraction mechanism.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Patricia Crumple*  
(Division 3, Off)  
Division of Control, Infection Control,  
and General Hospital Devices

510(k) Number 1982471

Prescription Use X Over-the-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)