K080877

OCT 21 2008

SECTION 5

Abbreviated 510(k) Summary

This 510(k) summary has been prepared in compliance with 21 CFR 807.92.

Applicant:	Unilife Medical Solutions Limited 35 Clarence Street Sydney NSW 2000 Australia Tel: +61 2 8346 6500 Fax: +61 2 8346 6511
Contact:	Michelle Gow Email: michelle.gow@unilife.com.au
Date Prepared:	March, 2008
Trade Name:	1mL Unitract® Insulin Syringe
Common Name:	Insulin Syringe
Classification:	Syringe, Piston; 21 CFR 880.5860; FMF; Class II
Predicate Devices:	1cc Insulin SafePro® Safety Syringe (K050134) BD Integra 1mL Syringe (K023752)
Device Description:	The 1mL Unitract® Insulin Syringe is a sterile, fixed needle, single use, insulin (U-100) syringe, consisting of a barrel and plunger assembly. The syringe is supplied in two needle sizes, being 27G x ½" and 29G x ½". The devices function in a manner similar to standard syringes for filling and mixing insulin and subcutaneous injection, but also incorporates a sharps injury prevention (automatic needle retraction) and reuse prevention (auto disable) feature. The sharps injury prevention feature allows for automatic and full retraction of the needle into the syringe barrel immediately after the full dose has been expelled; where the rate of retraction may be controlled by the user. The reuse prevention feature also engages immediately after retraction, which prevents further movement of the plunger in either direction.
Indications for Use:	The syringe as supplied is a device with a small barrel, plunger and fixed needle, calibrated in units of insulin (U-100), to be used to administer (infuse) insulin subcutaneously. It incorporates features that include reuse prevention and sharps injury prevention.

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Substantial Equivalence:

The 1mL Unitract® Insulin Syringe has identical indications for use and similar features to the cited predicate # K050134 which is to infuse insulin subcutaneously; whilst incorporating a sharps injury prevention feature. In addition, the spring based mechanism of the cited predicate # K023752; and how this mechanism is integrated within the design of the 1mL Unitract® Insulin Syringe do not raise new questions of safety and effectiveness.

Technological Characteristics:

The 1mL Unitract® Insulin Syringe has similar needle retraction mechanisms to the cited predicate # K050134. The syringe is filled; and at the end of the injection stroke once the full dose has been expelled, the plunger engages the needle to allow retraction into the syringe barrel. The cited predicate device relies on manual retraction and plunger fracture, where the 1mL Unitract® Insulin Syringe uses a spring based mechanism to retract the needle. The auto disable feature of the 1mL Unitract® Insulin Syringe is integrated within the plunger design, where after full retraction, the plunger engages with the collar outer to prevent movement of the plunger in either direction. This feature requires no secondary action by the user to disable the syringe.

The characteristics of the 1mL Unitract® Insulin Syringe spring based mechanism are similar to the technology of the cited predicate # K023752. The spring mechanism of this predicate device is located at the distal end of the syringe which facilitates the retraction of the needle into the plunger. The 1mL Unitract® Insulin Syringe spring mechanism is located on the proximal end of the syringe to allow retraction into the barrel.

The design of the 1mL Unitract® Insulin Syringe integrates the technological design characteristics of the cited predicates, and having similar operating procedures for filling and mixing insulin, aspiration and injection, has been demonstrated to have no significant differences.

The syringe components are manufactured from USP Class VI materials and stainless steel.

Non Clinical Performance Data:

Mechanical performance tests were conducted to verify the device meets design specifications based on the requirements of the FDA Consensus Standard *ISO 8537:1991 Sterile single-use syringes, with or without needle, for insulin* and the voluntary standard *AS 1077:1992, Single-use syringes (sterile) for the injection of 100 units per millilitre insulin (U-100).*

Additional performance testing was conducted on the safety features relating to peak activation forces of the retraction mechanism, spring reaction forces and forces to override the auto disable feature.

Chemical testing included Reducing (Oxidisable) Matter, Extractable Trace Metals, Non-Volatile Residue, pH and chemical residues (EO Sterilisation).

Biocompatibility testing of the finished devices included Cytotoxicity and Pyrogens; with all materials in the fluid path meeting USP Class VI requirements.

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Sterilisation processes are validated to European Standard *DIN EN 550:1994, Sterilisation of medical devices - Validation and routine control of ethylene oxide sterilisation* to a sterility assurance level (SAL) of 10^{-6}.

Manufacturing process control requires functional, chemical and biological tests be performed on each production lot number.

Conclusion:

The 1mL Unitract® Insulin Syringe with 27G x ½" and 29G x ½" needles submitted in this 510(k) is determined as substantially equivalent to the cited predicate devices based on performance testing, intended use and design principles of operation and technology, used for the subcutaneous infusion of insulin. Any differences cited do not raise any new questions of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2008

Ms. Michelle Gow
Quality and Regulatory Affairs Director
Unilife Medical Solutions Limited
Level 5, 35 Clarence Street
Sydney, NSW
AUSTRALIA 2000

Re: K080877
Trade/Device Name: 1mL Unitract® Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: September 4, 2008
Received: September 8, 2008

Dear Ms. Gow:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4

Indications for Use

510(k) Number (if known): Unknown

Device Name: 1mL Unitract® Insulin Syringe

Indications for Use:

The syringe as supplied is a device with a small barrel, plunger and fixed needle, calibrated in units of insulin (U-100), intended to be used to administer (infuse) insulin subcutaneously. It incorporates features that include reuse prevention and sharps injury prevention

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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