K100998

UNILIFE medical solutions

SECTION 6

Traditional 510(k) Summary

AUG 30 2010

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

Applicant:	Unilife Medical Solutions Limited 633 Lowther Rd Lewisberry, PA 17339 Tel: 717-938-9323 Fax: 717-938-9364
Contact:	Melissa L. DeHass, Senior Manager, Regulatory Affairs Email: Melissa.dehass@unilife.com
Date Prepared:	26 July 2010
Trade Name:	1mL Unitract® Tuberculin Syringe
Common Name:	Piston Syringe
Classification:	Syringe, Piston; 21 CFR 880.5860; FMF; Class II
Predicate Devices:	Unitract Insulin Syringe (K093400); BD Integra Syringe (K023752)
Device Description:	The 1mL Unitract® Tuberculin Syringe is a sterile, fixed needle, single use, syringe, consisting of a barrel and plunger assembly. The syringe is supplied as 27G x 1/2". The devices function in a manner similar to standard syringes, 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 Unitract Tuberculin Syringe, as supplied, is a device with a small barrel, plunger, and fixed needle, calibrated in milliliters (0.01 increments) to be used to administer (infuse) medication subcutaneous, intramuscular, or intradermal. It incorporates features that include reuse prevention (auto-disable) and sharps injury prevention (automatic needle retraction).
Substantial Equivalence:	The 1mL Unitract® Tuberculin Syringe has similar indications for use to the cited predicates # K093400 and # K023752 which is to infuse drugs; whilst incorporating a sharps injury prevention feature.

	The device design and technology is identical to K093400. The design of the 1mL Unitract® Tuberculin Syringe does not raise new questions of safety and effectiveness based on its similarities to the cited predicates in terms of design and intended use.
Technological Characteristics:	The 1mL Unitract® Tuberculin Syringe has identical needle retraction mechanisms to the cited predicate # K093400. The syringe is filled and at the end of the injection stroke as the full dose has been expelled, the plunger engages the needle to allow retraction into the syringe barrel. The auto disable feature of the 1mL Unitract® Tuberculin 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® Tuberculin Syringe spring based mechanism are identical to the technology of the cited predicate # K093400. The 1mL Unitract® Tuberculin Syringe spring mechanism is located on the proximal end of the syringe to allow retraction into the barrel. The design of the 1mL Unitract® Tuberculin Syringe integrates the technological design characteristics of the cited predicate, and having similar operating procedures for aspiration and injection, has been demonstrated to have no significant differences. The syringe components are manufactured from biocompatible 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 and the voluntary standards. 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. 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® Tuberculin Syringe with 27G x 1/2" needle submitted in this 510(k) is determined as substantially equivalent to the cited predicate device based on performance testing, intended use and design principles of operation and technology,. 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Melissa L. DeHass
Senior Manager, Regulatory Affairs
Unilife Medical Solutions Limited
633 Lowther Road
Lewisberry, Pennsylvania 17339

AUG 30 2010

Re: K100998
Trade/Device Name: 1mL Unitract® Tuberculin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 26, 2010
Received: July 28, 2010

Dear Ms. DeHass:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

UNILIFE medical solutions

K100998

SECTION 5

Indications for Use

510(k) Number (if known): This submission

Device Name: 1mL Unitract® Tuberculin Syringe

Indications for Use:

The Unitract Tuberculin Syringe, as supplied, is a device with a small barrel, plunger, and fixed needle, calibrated in milliliters (0.01 increments) to be used to administer (infuse) medication subcutaneous, intramuscular, or intradermal. It incorporates features that include reuse prevention (auto-disable) and sharps injury prevention (automatic needle retraction).

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K100998