K031062

MAY 2, 2003

Appendix G

510(k) Summary

510(k) Summary of Safety and Effectiveness
for the TMD™ 1ml Safety Syringe
(FA11 Series 1ml/FA51 Series U-100 Insulin / FA71 Series Tuberculin)
(per 21CFR807.92)

1. SPONSOR

Taiject Medical Device Co., Ltd.
10F, No300, Section 2
Chung Feng Road
Chu Tung Town, Hsin Chu
Taiwan 310
Republic of China
Tel: 886 3 595 9986
Fax: 886 3 595 9950
Contact person: Mr. David Huang
Date Prepared: March 28, 2003

2. DEVICE NAME

Proprietary Name:	TMD™ 1ml Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin / FA71 Series Tuberculin)
Common/Usual Name:	Safety Syringe
Classification Name:	Piston syringe (FMF) Anti-Stick Syringe (MEG)

3. Predicate Device (Legally Marketed Device):

Legally Marketed Device: TMD™ Safety Syringe (FA12 Series 3 ml/FA13 Series 5 ml) with 510K number K022278.

4. DEVICE DESCRIPTION

The TMD™ 1ml Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin / FA71 Series Tuberculin) is a single use, sterile, disposable syringes that is designed to reduce the risk of sharps injuries. The insulin syringe has scale lines in insulin units. The Tuberculin syringe has scale lines of Tuberculin.

5. INTENDED USE

--- The TMD™ 1ml Safety Syringe (FA11 Series 1ml) is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe reuse. It is a single use, disposable and manual retractable safety syringe that is intended for injection of fluids into the body after the aspiration of fluid.

--- The TMD™ 1ml Insulin Safety Syringe (FA51 Series U-100 Insulin) is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe reuse and is a single use, disposable and manual retractable safety syringe which is intended for use for subcutaneous injection of Insulin

--- The TMD™ 1ml Tuberculin Safety Syringe (FA71 Series Tuberculin) is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe reuse and is a single use, disposable and manual retractable safety syringe which is intended to use for the three types of injection(subcutaneous, intra-dermal and intra-muscular) of Tuberculin.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same as the legally market device, TMD™ Safety Syringe (FA12 Series 3 ml/FA13 Series 5 ml) with 510K number K022278 and TMD™ Safety Syringe (FA14 Series 10 ml/FA15 Series 20 ml) with 510K number K023458.

7. PERFORMANCE DATA

Performance data has been generated in compliance with the design control requirement and appropriate standards. The result demonstrated equivalent to the predicate devices.

Additional performance data was conducted to demonstrate the compliance with ISO8537 (Insulin Syringes) specification.

8. Additional Biocompatibility and Sterility evaluation:

Additional biocompatibility tests were performed. None of the tests indicates any

issues of the biocompatibility.

Additional sterility validation was performed in the process control to demonstrate the Sterility Assurance Level (SAL) of 10^{-6}.

9. COMPARISON INFORMATION

Comparison of the TMD™ 1ml Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin / FA71 Series Tuberculin) with Legally Marketed Device TMD™ Safety Syringe (FA12 Series 3ml/FA13 Series 5ml)

	Submission Device	**Legally Market Device**
	TMD™ 1ml Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin / FA71 Series Tuberculin)	TMD™ Safety Syringe (FA12 Series 3ml/FA13 Series 5ml)
Indications for Use	As a single use, hypodermic syringe. Safety feature protects after administration.	As a single use, hypodermic syringe. Safety feature protects after administration.
Volume (ml)	1ml	3ml/5ml
Needles Gauge	25~31Garge 5/8" or Shorter	18-25Garge 11/2" or Shorter
Needle Connection	Fixed needle	LuerLock LuerSlip
Safety Features	Active safety feature, manually activated by users	Active safety feature, manually activated by users
Syringe Type	Plunger, Antistick with fixed needles	Plunger, Antistick with hypodermic needles
Material	Piston-Butyl Rubber Barrel, plunger, Needle holder – Polypropylene Lubricant	Piston-Butyl Rubber Barrel, plunger, Needle holder – Polypropylene Lubricant

171

	shipping cartons.	

In summary, TMD™ 1ml Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin / FA71 Series Tuberculin) is a smaller version of the legally marketed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2003

Taiject Medical Device Company Limited
C/O Dr. Jim-Son Chou
Achevé Technology, Incorporated
P.O. Box 8853
Newport Beach, California 92658

Re: K031062
Trade/Device Name: TMD™ 1ml Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin/ FA71 Series Tuberculin)
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 28, 2003
Received: April 15, 2003

Dear Dr. Chou:

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.

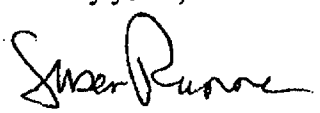
1

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) 594-4618. 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

K031062

510(k) Number (if known):

Device Name: TMD™ 1ml Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin / FA71 Series Tuberculin)

Indications For Use:

--- The TMD™ 1ml Safety Syringe (FA11 Series 1ml) is intended for injection of fluids into the body after the aspiration of fluid.

--- The TMD™ 1ml Insulin Safety Syringe (FA51 Series U-100 Insulin) is intended for use for subcutaneous injection of Insulin.

--- The TMD™ 1ml Tuberculin Safety Syringe (FA71 Series Tuberculin) is intended for intra-dermal injection of Tuberculin.

All the three syringes above incorporate a safety feature that is designed to aid the reduction of needlestick injuries and the potential of syringe reuse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)
other than maulen
maulen use

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

510(k) Number: K031062