NOV 7 2002 K023458

# 510(k) Summary of Safety and Effectiveness
## for the TMD Safety Syringe™ (FA14 Series 10ml/FA15 Series 20ml)
*(per 21CFR807.92)*

## 1. SPONSOR

Taiject Medical Device Co., Ltd.
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Contact person: Mr. David Huang
Date Prepared: Oct.12, 2002

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) |
| Common/Usual Name: | Safety Syringe (with or without needle) |
| Classification Name: | Piston syringe /Anti-Stick Syringe<br>Hypodermic single lumen needle |

## 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™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) is a sterile, single use and disposable, 10 ml & 20ml piston syringe, provided with or without needle in various product configurations. The TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) is similar in appearance, size, materials, operation, and purpose to other conventional single use, sterile, disposable syringes.

## 5. INTENDED USE

The TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) 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 injection of fluids into or withdraw from the body.

## 6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same as the legally market device, TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml).

## 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.

## 8. COMPARISON INFORMATION

**Comparison of the TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) with Legally Marketed Device TMD™ Safety Syringe (FA12 Series 3ml/FA13 Series 5ml)**

| | **Submission Device** | **Legally Market Device** |
|---|---|---|
| | TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) | 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) | 10ml/20ml | 3ml/5ml |
| Needles Gauge | 18-25Garge 11/2" or Shorter | 18-25Garge 11/2" or Shorter |
| Needle | LuerLock | LuerLock |

| Connection | LuerSlip | LuerSlip |
|---|---|---|
| Safety Features | Active safety feature, manually activated by users | Active safety feature, manually activated by users |
| Syringe Type | Plunger, Antistick with hypodermic 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 |
| Color | Parts- Clear Printing-Black | Parts- Clear Printing-Black |
| Labeling | The same format/description as the previously marketed devices | |
| Package | The same as the previously marketed devices. Except there are 400units in the shipping cartons. | There are 1800(without needle) and 1600(with needle) in the shipping cartons. |

In summary, TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) is a larger version of the legally marketed TMD™ Safety Syringe (FA12 Series 3ml/FA13 Series 5ml).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Taiject Medical Device Company Limited
C/O Dr. Jim-Son Chou
Achevé Technology, Incorporated
19502 Sierra Mia Road
Irvine, California 92612

Re: K023458
Trade/Device Name: TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml)
Regulation Number: 880.5860 and 880.5570
Regulation Name: Piston Syringe and Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MEG and FMI
Dated: October 12, 2002
Received: October 15, 2002

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.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023458

510(k) Number (if known):

Device Name: Taiject Medical Device Co., Ltd TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml)

Indications For Use:

The TMD™ Safety Syringe (FA14 Series 10ml/FA15 Series 20ml) is designed as an anti-stick syringe to reduce the risk of sharp injuries and the potential for syringe reuse and is a single use, disposable, manual retractable safety syringe which is intended for injection of fluids into and withdraw fluid from the body.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K023458

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)