APR 5 2005

K050134

SECTION VIII

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
for 1cc Insulin SafePro* Safety Syringe

1. REGULATORY AUTHORITY

Safe Medical Device Act of 1990, CFR 807.92.

2. CONTACT PERSON

C. Y. Lin (Ms)
Manager, Quality Assurance & Regulatory Affairs
FORMOSA MEDICAL DEVICES, INC.

U.S. Liaison Office
11497 Columbia Park Drive West, Suite #9
Jacksonville, FL 32258

3. NAME OF MEDICAL DEVICE

Classification Name:	Syringe, Antistick
Classification Code:	MEG
Common/Usual Name:	Syringe
Proprietary Name:	1cc Insulin SafePro* Safety Syringe

4. DEVICE CLASSIFICATION

The General Hospital Panel has classified Antistick Syringes (21CFR880.5860) into Class II, Special Controls under section 513 of the Act.

5. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The 1cc Insulin SafePro* Safety Syringe is essentially equivalent to:

A) B-D Conventional hypodermic and insulin syringe, K980580, and
B) The 1cc SafePro Safety Syringe, K022063, in design, materials, instructions for use, and product claims.

*Trademark

6. INTENDED USE

The primary intended use for the 1cc Insulin SafePro* Safety Syringe is aspirating and infusing insulin fluid.

The secondary intended use for the 1cc Insulin SafePro* Safety Syringe is for needlestick protection; the device may aid in the reduction of needlestick injuries.

7. DESCRIPTION OF DEVICE

The 1cc Insulin SafePro* Safety Syringe consists of a syringe assembly and a needle assembly. The device has a built-in safety feature to reduce the risk of accidental needlestick injuries. Other than scale graduation for use with U-100 strength insulin, the 1cc Insulin SafePro* Safety Syringe is essentially identical to the legally marketed 1cc SafePro* Safety Syringe in design and materials of construction.

8. SUMMARY OF MATERIAL TESTING

The materials of construction of the 1cc Insulin SafePro* Safety Syringe are identical to those for the SafePro* Safety Syringe and 1cc SafePro Safety Syringe. Those materials were already tested for material safety and biocompatibility as indicated in previous 510(K) submissions, K012726 and K022063. Therefore, no new biocompatibility tests are necessary.

9. SUMMARY OF SIMULATED USE STUDY

The safety feature and other functional and performance characteristics of the 1cc Insulin SafePro* Safety Syringe are identical to those for the SafePro* Safety Syringe and 1cc SafePro* Safety Syringe. Those features and characteristics were already verified and validated as shown in the two previous 510(k) notifications K012726 and K022063. Therefore, no new tests are necessary.

10. CONCLUSION

The results obtained indicate that the 1cc Insulin SafePro* Safety Syringe is safe and effective for its intended use.

*Trademark

COMPARISON MATRIX
1cc Insulin SafePro* Safety Syringe, B-D Conventional Syringe, and 1cc SafePro* Safety Syringe

This matrix was developed in accordance with the ODE Guidance titled "Supplementary Guidance on the Content of Premarket Notification [510(K)] Submissions for Medical Device with Sharp Injury Prevention Features (March, 1995)".

Factor	1cc Insulin SafePro* Safety Syringe	B-D Conventional Insulin Syringe	1cc SafePro* Safety Syringe
510(K) Number	To Be Assigned	K980580	K012726
Intended Use and Claims			
• Same Intended Use	Yes	Yes	Yes
• Tissue Puncture Device	Yes	Yes	Yes
• Sharps Injury Prevention Feature	Yes	No	Yes
• Reduces Risks of Accidental Needlesticks	Yes	No	Yes
• Delivers fluid to or draw blood from patient, short term	Yes	Yes	Yes
• Conventional Insertion Technique with minimal training	Yes	Yes	Yes
Technological Features			
• Same Technology Features	No	No	Yes
• Safety Mechanism - Manual Actuation	Yes	Not Applicable	Yes
• Safety Mechanism Remains Activated During Disposal	Yes	Not Applicable	Yes
• Safety Mechanism is an Integral Part of the Device	Yes	Not Applicable	Yes
Material of Construction			
• Needle • Needle Hub	• Stainless Steel •PP*	• Stainless Steel •PP	•Stainless Steel •PP* with more needle gauges (Different hub colorants)
• Barrel, Plunger, Sheath	PP	PP	PP
• Gasket	Synthetic Rubber	Synthetic Rubber	Synthetic Rubber

*PP – Polypropylene resin

*Trademark

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2005

Ms. C.Y. Lin
Manager, Quality Assurance & Regulatory Affairs
FORMOSA MEDICAL DEVICES, INCORPORATED
16F, No. 182, Section 2
Tunhua South Road
Taipei
TAIWAN, R.O.C. 106

Re: K050134
Trade/Device Name: 1cc Insulin* SafePro Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: January 21, 2005
Received: January 24, 2005

Dear Ms. Lin:

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.

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 (240) 276-0115. 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/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

Indications for Use

510(k) Number (if known):

K050134

Device Name:

1cc Insulin SafePro* Safety Syringe

Indications For Use:

The primary indicated use for the 1cc Insulin SafePro* Safety Syringe is for aspirating and injecting insulin fluid.

The secondary indicated use for the 1cc Insulin SafePro* Safety Syringe is for needlestick protection; the device may aid in the reduction of needlestick injuries.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (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 [illegible] Hospital,
Infection Control, Dental Devices

(Optional Format 3-10-98) 510(k) Number K050134

*Trademark