AUG - 5 2003

510(K) Application Number: K031830

SECTION VIII

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
for SafePro* *Plus* Safety Syringe

1. REGULATORY AUTHORITY

Safe Medical Device Act of 1990, CFR 807.92.

2. CONTACT PERSON

Joseph J. Chang, Ph.D., PE
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:	SafePro* ***Plus*** Safety Syringe

4. DEVICE CLASSIFICATION

The General Hospital Panel has classified Antistick Syringes (21CFR880.5600) into Class II, Special Controls under section 513 of the Act.

5. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The SafePro* ***Plus*** Safety Syringe is substantially equivalent to:

A) B-D Luer Lok conventional syringe with regard to the conventional syringe/needle and intended use,
B) VanishPoint™ syringe with regard to retraction of the needle assembly into the barrel for needlestick protection feature, and
C) The previously approved SafePro Safety Syringe Syringes (K012726) in design, Instructions for Use, and product claims.

6. INTENDED USE

The primary intended use for the SafePro* ***Plus*** Safety Syringe is for general purpose use in aspirating and injecting fluid.

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

7. DESCRIPTION OF DEVICE

The SafePro* ***Plus*** 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.

8. SUMMARY OF MATERIAL TESTING

The materials of construction for the SafePro* ***Plus*** Safety Syringe are identical to those for the SafePro* Safety Syringe which were already tested for biocompatibility by an independent, ISO certified, outside testing laboratory. Test results indicated that the entire SafePro* Safety Syringe meets ISO 10993-1 and US FDA G-95 requirements.

9. SUMMARY OF SIMULATED USE STUDY

A total of 500 SafePro* ***Plus*** Safety Syringes were evaluated by 50 participants. No sharps injuries or failures of the safety mechanism occurred. Successful completion of the study supports the claim that SafePro* ***Plus*** Safety Syringe may reduce the risk of accidental needlestick injuries. The positive responses from the Evaluators regarding functional and performance aspects also indicated that the SafePro* ***Plus*** Safety Syringe meets customer requirements.

10. CONCLUSION

The results obtained from bench testing, material safety, and simulated use tests indicate that the SafePro* ***Plus*** Safety Syringe is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2003

Formosa Medical Devices, Incorporated
C/O Joseph J Chang
General Manager and Chief Technology Officer
Safepro USA, Incorporated
11497 Columbia Park Drive West Suite #9
Jacksonville, Florida 32258

Re: K031830
Trade/Device Name: SafePro* Plus Safety Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: June 11, 2003
Received: June 13, 2003

Dear Dr. Chang:

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 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

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

INDICATIONS FOR USE

Device Name

SafePro* ***Plus*** Safety Syringe

Indication for Use

The primary indicated use for the SafePro* ***Plus*** Safety Syringe is for general purpose use in aspirating and injecting fluid.

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

Patricia Cicenia

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

510(k) Number: K031830

(Please don not write below this line-Continue on another page if needed)
Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter _____
Per 21 CFR 801.109
(Optional Format 1-2-96)

*Trademark