K 983647

510(k) Summary

ECHO-COAT™ Ultrasound Needles

Common/Classification Name: Manual Surgical Instrument, 21 CFR 878.4800

STS Biopolymers, Inc.
336 Summit Point Drive
Henrietta, NY 14467

Contact: Michael Violante, Prepared: October 12, 1998

A. LEGALLY MARKETED PREDICATE DEVICES

The **ECHO-COAT™ Ultrasound Needles** are substantially equivalent to the Disposable Chiba Biopsy Needle for Use with Ultrasound manufactured by Cook (K851957), as modified with the "EchoTip" for ultrasound imaging visibility.

B. DEVICE DESCRIPTION

STS Biopolymers, Inc. will purchase in bulk currently marketed needles designated by application (biopsy, aspiration, amniocentesis, etc.), needle type (spinal, Chiba, Franseen, other), needle gauge (11 to 30), and length (3 to 20 cm), and then apply a polymer coating. The coating, called ECHO-COAT™, is visible in ultrasound images, assisting with positioning. The coated needles will be repackaged as single-use devices, sterilized with EtO, and distributed commercially under the STS Biopolymers, Inc. name.

C. INTENDED USE

ECHO-COAT™ Ultrasound Needles are easily visualized on ultrasound images produced by currently available ultrasound imaging devices operating between 1 and 20 MHz. The needles are biocompatible when used according to their intended use. The specific indications for use for the needles purchased for coating will be assumed for the coated product.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **ECHO-COAT™ Ultrasound Needles** have similar, but not identical, technological characteristics as the predicate devices. The

differences could affect safety and effectiveness, e.g., the biocompatibility of the polymer coating as compared to stainless steel. However, the new characteristics do not raise new types of safety and effectiveness questions and there are readily available scientific tests (e.g., biocompatibility tests) to assess the effects of the new characteristics (the material). STS is providing performance data to demonstrate equivalence where necessary.

E. TECHNOLOGICAL CHARACTERISTICS

The needles that are purchased for coating by STS Biopolymers, Inc. obviously have the same technological characteristics as the coated product that will be marketed by STS Biopolymers, Inc.. The additional characteristic of the coating is new, but it does not raise new types of safety and effectiveness questions. Biocompatibility is required of all needles and can be assured through testing using accepted standards. Ultrasound visibility is obtained through the new coating rather than by etching the surface as in the predicate device. However, there are readily available methods for determining ultrasound visibility also. Through the presentation of the resulting performance data, STS Biopolymers, Inc. has demonstrated that its proposed product is substantially equivalent to the predicate device.

F. TESTING

STS Biopolymers, Inc. carried out performance testing on the **ECHO-COAT™ Ultrasound Needles.** This testing addressed the following issues:

(1) Sterilization

(2) Package Integrity

(3) Biocompatibility

(4) Imaging Performance Testing

All of the results demonstrate substantial equivalence.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K983647
Trade Name: ECHO-COAT™ Ultrasound Needle
Regulatory Class: I
Product Code: MJG
Dated: October 16, 1998
Received: October 16, 1998

Dear Dr. Athey:

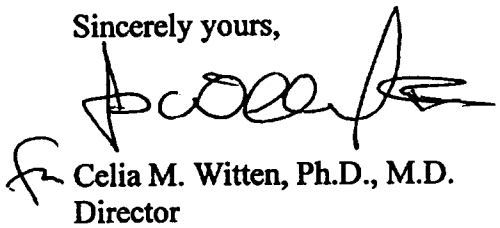
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: ECHO-COAT™ Ultrasound Needle

Indications For Use:

The ECHO-COAT™ Ultrasound Needle is indicated for use where improved visibility on ultrasound images is required compared to an uncoated needle. The coated needle also assumes the specific indications for use of the currently marketed uncoated needle, for example biopsy, amniocentesis, vascular access, aspiration, and drainage needles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983647