

OCT 14 1999

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner Meditech, Inc. („Greiner“) is submitting a 510(k) premarket notification for the Ecomed[®] Scalp Vein Set. The Ecomed[®] Scalp Vein Set is a sterile winged needle bonded to a flexible tubing with a female luer adapter. The female luer is provided with a protective cap on the end.

Greiner is claiming substantial equivalence to Becton Dickinson's VACUTAINER[®] Brand Blood Collection Set (K980414). Both scalp vein sets (butterfly needles) have the same intended use (i.e. withdrawal of venous blood) and contain the same materials. The material of the ECOMED[®] needle is stainless steel and is the same material used for the BD needle. Both the ECOMED[®] and BD needle protector sleeves covering the short end of the needle are made from rubber, and both the ECOMED[®] and BD needle shields are made from extruded plastic.

Non-cytotoxicity was demonstrated in testing which was performed in accordance with the ISO 10993, along with other tests such as endotoxin testing.

The ECOMED[®] Scalp Vein Set will be marketed separately and as a kit assembled with Greiner's 510k cleared VACUETTE[®] Holdex[®] holder (K980768).

Greiner's 510(k) has been submitted on June 25, 1999, by Douglas L. Harris, Managing Director, Greiner Meditech, Inc., 260 Gateway Drive, Suite 17A, Bel Air, Maryland, 21014 (410-836-8228).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Mr. Douglas L. Harris
Greiner Meditech, Inc.
260 Gateway Dr., Suite 17A
Bel Air, MD 21014

Re: K992145
Trade Name: Ecomed® Scalp Vein Set
Regulatory Class: II
Product Code: FOZ
Dated: September 15, 1999
Received: September 20, 1999

Dear Mr. Harris:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

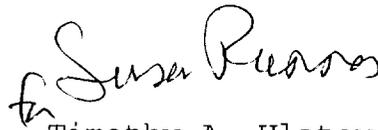
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may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices 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) 594-4692. 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,



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

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known) _____

Device Name: ECOMED® Scalp Vein Set

Indications for Use: The Ecomed® Scalp Vein Set is a winged blood collection needle with a tubing used for the collection of venous blood.

Prescription Use X

Over-The Counter Use _____

Patricia Cuervo

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

510(k) Number K992145