K973620

DEC 17 1997

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner Meditech, Inc. („Greiner") is submitting a 510(k) premarket notification for it's Greiner Vacuette® Multi- sample needle. The Vacuette® Multi- sample needle is a tubular stainless steel device sharpened at both ends, one end to withdraw blood, and the other end to be threaded into a needle holder which is used to guide the needle into an evacuated blood collection tube..

Greiner is claiming substantial equivalence to Gainor Medical's Suresharp® needles (K950159). Both multi-sample needles have the same intended use and contain the same material. The material of the Greiner needle is stainless steel and is the same material used for the Gainor needle. The material of the hub for both needles is made from polypropylene. The sleeve covering the short end of the needle is made from rubber. The needle shield is made from polypropylene. The equivalency of the needles is certified by a statement that the needles are the same and purchased from the same supplier in Japan.

Greiner's 510(k) has been submitted on Monday, September 22, 1997, 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

Mr. Doug Harris
Managing Director
Greiner Meditech, Incorporated
260 Gateway Drive, Suite 17A
Bel Air, Maryland 21014

DEC 17 1997

Re: K973620
Trade Name: Vacuette Multi-Sample Needle
Regulatory Class: II
Product Code: FMI
Dated: September 18, 1997
Received: September 23, 1997

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 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) 594-4618. 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" (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) K973620

Device Name: VACUETTE® Multi-sample Needle

Indications for Use: For use in venous blood collection

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973620

Prescription Use X

Over-The Counter Use _____