JUL 15 1998

K981619

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner Meditech, Inc. ("Greiner") is submitting a 510(k) premarket notification for it's Greiner Vacuette® Multiple Sample Luer Adapter. The Greiner Vacuette® Multiple Sample Luer Adapter is a device of which one end is a plastic male luer adapter and the other end is a sharpened stainless steel needle. The needle end of the luer adapter is epoxy bonded to the plastic upper end (hub) and is covered by a rubber sheath. The luer adapter is threaded into a needle holder for the purposes of attaching a butterfly needle or luer needle for use in venous blood collection. The luer adapter is a sterile, single-use disposable device.

Greiner is claiming substantial equivalence to Gainor Medical's SURESHARP® Luer Adapter (K950159). Both luer adapters have the same intended use and contain the same material. The equivalency of the luer adapters is certified by a statement that the luer adapters are the same and purchased from the same supplier in Japan.

Greiner's 510(k) has been submitted on Wednesday, April 30, 1998 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

JUL 15 1998

Mr. Douglas L. Harris
Managing Director
Greiner Meditech, Incorporated
P.O. Box 943
Bel Air, Maryland 21014

Re: K981619
Trade Name: VACUETTE® Multiple Sample Luer Adapter
Regulatory Class: II
Product Code: FMI
Dated: May 6, 1998
Received: May 6, 1998

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 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). 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 requirements, 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) 594-4692. 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"(21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for 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) K981619

Device Name: VACUETTE® Multiple Sample Luer Adapter

Indications for Use: For use in venous blood collection with attached butterfly needle or luer needle.

Rebecca Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981619

Prescription Use X

Over-The Counter Use _____