I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR - 9 1998

K980768

Greiner Meditech, Inc. („Greiner") is submitting a 510(k) premarket notification for it's Greiner VACUETTE® Holdex® Holder. The VACUETTE® Holdex® Holder is a single-use disposable plastic device to be used in routine venipuncture procedures using butterfly needles or luer needles. Sterile and non-sterile versions are available. The sterile version of VACUETTE® Holdex® is manufactured from polystyrene plastic and is sterilized by electronic beam. The non-sterile version is autoclavable and is manufactured from polycarbonate plastic.

Greiner is claiming substantial equivalence to Becton Dickinson's pre-amendment VACUTAINER® Brand holder in combination with Becton Dickinson VACUTAINER® Brand luer adapter (K921520). The Becton Dickinson product is sold as a sterile combination set as VACUTAINER® Brand Direct Draw Adapter - Multiple sample luer adapter with pre-attached needle holder (catalog no. 364894). Both devices have the same intended use and both are manufactured from plastic.

Greiner's 510(k) has been submitted on February 26th, 1998 by Doug Harris, Managing Director, Greiner Meditech, Inc., 260 Gateway Drive, Suite 17A, Bel Air, Maryland 21014 (T: 410-836-8228).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 1998

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

Re: K980768
Trade Name: Vacuette Holdex
Regulatory Class: II
Product Code: FMI
Dated: February 27, 1998
Received: February 27, 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 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) _____

Device Name: VACUETTE® Holdex®

Indications for Use: To be used in routine venipuncture procedures using butterfly needles and/or hypodermic luer needles.

Prescription ___X___ Over-the-Counter _____

Patricia Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980768