JUL 1 2 2001

July 11, 2001

510(k) SUMMARY

K011786

CONTACT:

Douglas L. Harris
Greiner Vacuette North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICES:

Trade Name:	Vacuette® Safety Blood Collection Set
Common Names/Descriptions:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Short-Term

PREDICATE DEVICE:

Sherwood Medical Angel Wing™ Safety Blood Collection Set (K912563)

DEVICE DESCRIPTION:

INTENDED USE: The VACUETTE® Safety Blood Collection Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a female luer adapter.

PRODUCT DESCRIPTION: The VACUETTE® Safety Blood Collection Set is used in routine venipuncture procedures. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

The safety feature is easily operated through the release of a latch mechanism whereby the user slides a winged cover over the needle, as it is removed from the patient. Once the needle is covered, the safety cover locks in place. This mechanism is substantially equivalent to that of the Monoject® Angel Wing Blood Collection Set.

The **VACUETTE®** Safety Blood Collection Set will be available in 80 configurations to include needle gauge (10 gauge sizes), needle length (2 lengths) and tubing length (4 lengths).

The devices are packaged as sterile and are labeled for single use only. There is no ability to clean and reuse these devices. The results of biocompatibility data support the equivalence of the predicate device and include sterility, pyrogenicity and systemic injection testing.

SUBSTANTIAL EQUIVALENCE:

The **VACUETTE®** Safety Blood Collection Set is substantially equivalent to the Monoject® Angel Wing Blood Collection Set in intended use, materials, biocompatibility, and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Greiner Vacuette North America, Incorporated
C/O Ms. Judi Smith
Sienna Partners, L.L.C
P.O. Box 103
Baldwin, Maryland 21013

Re: K011786
Trade/Device Name: Vacuette® Safety Blood Collection Set
Regulation Number: 880.5570
Regulatory Class: II
Product Code: FMI
Dated: June 8, 2001
Received: June 8, 2001

Dear Ms. Smith:

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,

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

Enclosure

510(k) Number (if known):

Device Name: **VACUETTE®** Safety Blood Collection Set

Indications For Use: The VACUETTE® Safety Blood Collection Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a female luer adapter. The VACUETTE® Safety Blood Collection Set is used in routine venipuncture procedures. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K01 1786