510(K) SUMMARY

K072320 August 17, 2007

CONTACT:

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

SEP 14 2007

NAME OF DEVICES:

Trade Name:	**VACUETTE**® QUICKSHIELD Complete
Common Names/Descriptions:	Evacuated Blood Collection Tube Holder
Classification Name:	Needle, Hypodermic, Single Lumen

PREDICATE DEVICE:

Greiner **VACUETTE**® QUICKSHIELD safety holder - K033478;
VACUETTE® Multi-Sample Needles - K973620;
VACUETTE® VISIO PLUS Needles - K061483

DEVICE DESCRIPTION:

Intended Use: The QUICKSHIELD Complete is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions. This device 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. VACUETTE® VISIO PLUS Blood Collection Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.

SUBSTANTIAL EQUIVALENCE:

The Greiner **VACUETTE**® QUICKSHIELD Complete is substantially equivalent to the Greiner **VACUETTE**® QUICKSHIELD safety holder (K033478), the **VACUETTE**® Multi-Sample Needles (K973620), and the **VACUETTE**® VISIO PLUS Needles (K061483) in intended use, materials, and sterilization process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2007

Greiner Bio-One North America, Incorporated
C/O Ms. Judi Smith
Director, IVD/Medical Devices
Beaufort Advisors Limited Liability Company
500 East Main Street, Suite 1301
Norfolk, Virginia 23510

Re: K072320
Trade/Device Name: Greiner **VACUETTE**® QUICKSHIELD Complete
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 17, 2007
Received: August 20, 2007

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

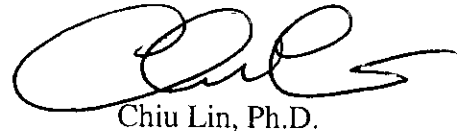
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.2. INDICATIONS FOR USE

Indication for Use

510(k) Number (if known):

Device Name: Greiner **VACUETTE**® QUICKSHIELD Complete

Indication For Use:

The QUICKSHIELD Complete is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions. This device 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. VACUETTE® VISIO PLUS Blood Collection Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of Device Evaluation

510(k)_____

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

510(k) Number: K972324