K061483

July 11, 2006

510(k) SUMMARY

CONTACT:

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

AUG 14 2006

NAME OF DEVICE:

Trade Name:	**VACUETTE**® VISIO PLUS Blood Collection Needles
Common Names/Descriptions:	Blood Collection Needles
Classification Name:	Needle, Hypodermic, Single Lumen

PREDICATE DEVICE: Greiner **VACUETTE**® Multi-Sample Needle (K973620)

DEVICE DESCRIPTION:

INTENDED USE: VACUETTE® VISIO PLUS Blood Collection Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner.

PRODUCT DESCRIPTION: VACUETTE® VISIO PLUS Blood Collection Needles are manufactured from stainless steel and are fitted with a safety valve at one end. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. The perforated label not only serves to simplify identification, but also acts as a seal of integrity. VACUETTE® VISIO PLUS Blood collection needles are a sterile single-use product. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.

The VACUETTE® VISIO PLUS Blood Collection Needles will be available in four configurations to include two needle gauge sizes (21G and 22G) and two corresponding needle lengths (25 mm [1 inch] and 38 mm [1 ½ inches]):

- Needle gauge = 21G; Front needle length = 25 mm [1 inch]
- Needle gauge = 22G; Front needle length = 25 mm [1 inch]
- Needle gauge = 21G; Front needle length = 38 mm [1 ½ inch]
- Needle gauge = 22G; Front needle length = 38 mm [1 ½ inch]

The needles are packaged as sterile and are labeled for single use only. There is no ability to clean and reuse these devices.

SUBSTANTIAL EQUIVALENCE:

The Greiner **VACUETTE®** VISIO PLUS Blood Collection Needles are substantially equivalent to the Greiner **VACUETTE®** Multi-Sample Needle (K973620) in intended use, materials, and general design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2006

Greiner Bio-One North America, Incorporated
C/O Ms. Judith J. Smith
Principal
Sienna Partners, L.L.C.
P.O. Box 103
Baldwin, Maryland 21013

Re: K061483
Trade/Device Name: Greiner **VACUETTE**® VISIO PLUS Blood Collection Needles
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 11, 2006
Received: July 12, 2006

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.

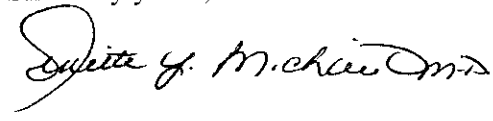
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

INTENDED USE STATEMENT

510(k) Number (if known): K061483

Device Name: Greiner **VACUETTE®** VISIO PLUS Blood Collection Needles

Indications For Use:

VACUETTE® VISIO PLUS Blood Collection Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner.

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off) Number: K061483

(Optional Format 1-2-96)