

MAR 20 1998

M. 510(K) Summary of Safety and Effectiveness

***Monoject® BlunTip™* I.V. Access Cannula with Vial Access Pin**

Submitted by: Sherwood - Davis & Geck
444 McDonnell Blvd.
Hazelwood, MO 63042

Contact: Stephen J. Tamsett,
Regulatory Affairs Manager

Date of Summary: December 16, 1997, 2/4/98

The *Monoject® BlunTip™* I.V. Access Cannula with Vial Access Pin products combine a new access pin with the currently marketed *BlunTip* I.V. Access cannula. The access pin and cannula, in combination, perform the same function as a hollow-bore needle when used for accessing the contents of a drug vial. The Vial Access device has been designed to improve I.V. drug administration safety for both the clinician and the patient. This product has been extensively tested to ensure product safety and efficacy.

The primary design goal of the Vial Access products is to eliminate the hazards associated with a sharp, hollow-bore hypodermic needle in I.V. drug administration. The brightly colored, sterile access pin enables users to pre-pierce the drug vial closure for subsequent access using a *BlunTip* cannula.

Hypodermic needles have been used for vial access for decades and are Pre-Amendment devices.

The *Monoject BlunTip™* I. V. Access Cannula included with the Vial Access product is currently marketed under 510(k) K960982.

The *Monoject BlunTip™* I. V. Access Cannula is substantially equivalent to the Becton Dickinson 18 gauge Hypodermic needle, and the *Monoject®* gauge hypodermic needles manufactured by Sherwood Davis and Geck. There are other products such as the Becton Dickenson Interlink* Multi-Dose Access Cannula and Baxter/Becton Dickinson Interlink* Multi-Dose Vial Access System.

The *Monoject BlunTip™* I. V. Access Cannula with Vial Access Picc is designed to provide needleless drug vial access. The sterile device is used to pre-pierce the rubber drug vial closure facilitating medication Access with the *BlunTip™* Cannula. Only one access pin penetration is required to enable *BlunTip™* Cannula access. Once drawn, the medication can be delivered through this pre-pierced I.V. port compatible with the *BlunTip™* Cannula.

Although there are no performance standards associated with this device, the testing and design features have shown that there are no new issues with safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 1998

Mr. Stephen J. Tamsett
Regulatory Affairs Manager, USA
Sherwood - Davis & Geck
444 McDonnell Boulevard
Hazelwood, Missouri 63042-2516

Re: K980062
Trade Name: Monoject® BlunTip™ I.V. Access Cannula with
Vial Access Pin
Regulatory Class: II
Product Code: FMI
Dated: January 6, 1998
Received: January 7, 1998

Dear Mr. Tamsett:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

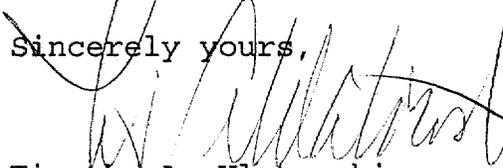
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (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

K980062

510(k) Number (if known)

Device Name: Sherwood-Davis & Geck Monoject® BlunTip™ I.V. Access Cannula with Vial Access Pin Device

Indications for Use: Sherwood-Davis & Geck Monoject® BlunTip™ I.V. Access Cannula with Vial Access Pin Device is designed to provide needleless drug access. The sterile access pin is used to pre-pierce the rubber drug vial closure, facilitating direct medication access with the BlunTip* cannula. Only one access pin penetration is required to enable repeated BlunTip* cannula access. Once drawn, the medication can be delivered through any pre-pierced I.V. port compatible with the BlunTip* cannula.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cervante
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K980062

Prescription Use OR
(Per 21 CFR 801.109)

Over-the-Counter Use _____
(optional format 1-2-96)

(Division Sign-off)

510(k) Number _____