K013006

510(k) Summary

FEB 0 6 2002

OVUS Capless Safety Needle

Common/Classification Name: Single lumen needle, 21 CFR 880.5570

OVUS Systems, Inc.
5004 Rittenhouse Street
Riverdale, MD 20737

Contact: Owais Mohammad, Prepared: November 26, 2001

A. LEGALLY MARKETED PREDICATE DEVICES

The **OVUS Capless Safety Needle**, when used with a standard commercially available syringe, is substantially equivalent to the Retractable Technologies Pop-N-Lok Syringe that was cleared for marketing by FDA under K946219 on December 28, 1995. It is also substantially equivalent to the Needle-Pro needle protection device that is manufactured by Concord Portex and cleared for marketing by FDA under K904198 and K911037.

B. DEVICE DESCRIPTION

The **OVUS Capless Safety Needle** is a retractable needle system that provides anti-sharps protection. The device is made of the following components: (1) a slotted plastic housing, (2) a needle with a tab on the hub that protrudes from the slot in the housing when installed, (3) a spring that fits over the metal needle shaft, (4) a collar bonded to the proximal end of the housing to prevent the needle from sliding out, (5) a locking pin to prevent reuse (tamper-proof version only), and (6) a dust cover for the distal end of the device.

The housing has a slot that allows the tab on the needle hub to slide toward the distal end and into the extended position with the needle fully exposed. At each end of the slot there is a short perpendicular slot that serves to lock the needle/tab in either the fully retracted or fully extended position. When extended, the spring is compressed and would tend to retract the needle unless it were locked in the extended position.

To use the device, the package is opened and a syringe of the appropriate diameter is inserted into the needle hub. The needle is

then unlocked and slid into the fully extended position and again locked. With the needle in the fully extended and locked position, the procedure is carried out as usual. Following the procedure, the needle is unlocked and retracted into the housing. When fully retracted, the needle is locked into the retracted position. For the tamper-proof version, the needle is permanently locked in the retracted position by pressing in the tamper-proof pin. The needle is then placed in an antisharps container.

C. INTENDED USE

The OVUS Capless Retractable Safety Needle, when used with a standard commercially available syringe, is intended to inject fluids into, or withdraw fluids from, parts of the body, including the applications of hypodermic injection, veinipuncture, and drawing of arterial blood. The needle is retracted after use to prevent accidental needle sticks.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **OVUS Capless Safety Needle** is a medical device, and it has similar, but not identical indications for use statement as the legally marketed predicate devices. In regard to the safety feature, the **OVUS Capless Safety Needle** has somewhat different technological characteristics as the predicate devices. However, the new characteristics do not raise new safety or effectiveness issues. Accepted scientific methods are available to assess the new characteristics. For those characteristics, performance data from simulated-use studies is provided. The performance data demonstrates that the **OVUS Capless Safety Needle** is substantially equivalent to the predicate devices.

E. TECHNOLOGICAL CHARACTERISTICS

The OVUS needle is made from the same materials as are the predicate devices--medical plastics and stainless steel.

The safety feature of the needle uses a different approach from the predicate devices. The Needle-Pro needle employs a protective cap that can be snapped over the needle following use. The VanishPoint needle and syringe uses a retractable needle as its safety feature, but the retraction is automatic once it is triggered, while the OVUS needle is manually operated for extension and retraction. The VanishPoint needle is retracted into the barrel of the syringe following use, while the OVUS needle is retracted into a protective housing, allowing the syringe to operate independently of the needle.

F. TESTING

Simulated-use studies were carried out to compare the performance of the OVUS needle with the two predicate devices using three different types of needle procedures, hypodermic injection, veinipuncture, and arterial blood draw. The participants in the three studies rated the OVUS Capless Safety Needle very close to the predicate devices on the functionality outcome measures.

In comparison to the Needle-Pro device, the OVUS needle was preferred in all but one of the six functionality measures in one study and in 3/6 in the other, though statistical significance was only obtained for 4/6 and 1/6 respectively. In comparison to the much more expensive and technologically complicated VanishPoint device, the OVUS needle was preferred on only 1/6 functionality measures, though the differences were very small and none were significant.

The participants rated the OVUS needle higher than the Needle-Pro needle on safety. In the primary analysis, equivalence was established in both studies. The participants expressed a slight (non-significant) preference for the safety feature of the OVUS needle compared to the VanishPoint needle.

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Ovus Systems
C/O Dr. T. Whit Athey
C.L. McIntosh & Associates
12300 Twinbrook Parkway, Suite 230
Rockville, Maryland 20852

Re: K013006
Trade/Device Name: Ovus Capless Safety Needle
Regulation Number: 880.5860
Regulation Name: Single Lumen Hypodermic with Anti-Shapes Feature
Regulatory Class: II
Product Code: MEG
Dated: November 27, 2001
Received: November 27, 2001

Dear Dr. Athey:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/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

K013006

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K013006

Device Name: OVUS Capless Safety Needle

Indications For Use:

The OVUS Capless Safety Needle, when used with a standard commercially available syringe, is intended to inject fluids into, or withdraw fluids from, parts of the body, including the applications of hypodermic injection, venipuncture, and drawing of arterial blood. The needle is retracted after use to prevent further needle sticks.

(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)

Patricia Cuenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
(510(k) Number K013006

TOTAL P.04