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SEP 29 2006

510K Premarket Notification Submission
Summary of Safety and Efficacy

Date of Preparation: September 12, 2006

Applicant: Vygon Corporation
2495 General Armistead Ave.
Norristown, PA 19403

Contact Individual: Courtney Smith, Regulatory Affairs Manager
610-539-9300 Ext. 110

Trade Name: Multicath Expert

Common Name: Intravascular Catheter

Regulation Number: 880.5200

Product Code: FOZ

Classification Name: Intravascular Catheter

Classification: Class II

Predicate Device Name: Multicath (K870067), Vantex (K992532 / K033250)

Device Description: The Multicath Expert catheters are a line of multilumen catheters which have an antimicrobial function. The polyurethane catheters are impregnated with the silver ion-based antimicrobial agent AgION^{tm} and are available in 2-, 3-, 4-, or 5-lumen catheters. Silver has been shown to have exceptional broad antimicrobial spectrum against bacteria and fungi including antibiotic resistant strains. The expert technology is based on an antimicrobial substance which is both mineral and bio-inert. It is neither an antibiotic nor an organic antiseptic; and the silver ions are released in low, non-toxic concentrations. Expert catheters release silver ions from their internal and external surfaces, and silver ions are released very gradually over an extended period of time, ensuring long-term efficacy. Biocompatibility and performance testing demonstrates the safety and efficacy of these devices.

The Multicath Expert catheters are as follows:

Description	Reference
Multicath Expert Catheters	8159.xxx, 8158.xxx, 8157.xxx, 8155.xxx

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Intended Use: The Vygon Multicath Expert Catheter is intended for use in patients who require short-term (less than 30 days) I.V. therapy. It may be used to administer hyperalimentation, antibiotics, chemotherapy, drugs for pain management or intravenous fluids. The catheters incorporate a silver based antimicrobial agent.

Technology Characteristics: Silver has been shown to have exceptional broad antimicrobial spectrum against bacteria and fungi including antibiotic resistant strains. The expert technology is based on an antimicrobial substance which is both mineral and bio-inert. It is neither an antibiotic nor an organic antiseptic; and the silver ions are released in low, non-toxic concentrations. Expert catheters release silver ions from their internal and external surfaces, and silver ions are released very gradually over an extended period of time, ensuring long-term efficacy.

Summary of Design Control Activities:

Biocompatibility testing of the material demonstrate that it is non-irritant and non-toxic. Performance testing demonstrates that the changes do not affect safety or efficacy. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: The only change between the predicate device (Multicath K870067) and the Multicath Expert is the addition of the Agion techniology. Biocompatibility testing, performance testing and risk assessment demonstrate that the Multicath Expert is safe and effective to use, when used in accordance with the supplied instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2006

Ms. Courtney Smith
Regulatory Affairs Manager
Vygon Corporation
2495 General Armistead Avenue
Norristown, Pennsylvania 19403

Re: K061250
Trade/Device Name: Vygon Multicath Expert Catheters
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: September 15, 2006
Received: September 18, 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 (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

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Indications for Use

510(k) Number (if known):

Device Name: Vygon Multicath Expert Catheters

Indications For Use:

The Vygon Multicath Expert Catheter is intended for use in patients who require Short-term (less than 30 days) I.V. therapy. It may be used to administer hyperalimentation, antibiotics, chemotherapy, drugs for pain management or intravenous fluids. The catheters are manufactured with a Pellethane-based AgION™ antimicrobial. The AgION™ uses silver as the antimicrobial agent.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K061250