Page 1 of 2
K062425

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SEP 15 2006

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: August 14, 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: Lifecath S

Common Name: Lifecath PICC

Regulation Number: 880.5970

Product Code: LJS

Classification Name: Percutaneous, implanted, long-term intravascular catheter

Classification: Class II

Predicate Device Name: Vascu-PICC (K030270)
Lifevac-PICC (K903648 and K983544)
Lifecath PICC PUR (K993442)

Device Description: The Lifecath S peripherally inserted central catheters and midline catheters are fabricated of barium impregnated silicone elastomer. The catheters are supplied with a guidewire to aid in insertion. The 60 cm PICC is available as a 2Fr, 3Fr, 4Fr, and 5Fr single lumen catheter, and 4Fr, 5Fr and 6Fr catheter. The 20 cm midline catheter is available as a 2Fr, 3Fr, 4Fr, and 5Fr single lumen catheter, and 4Fr, 5Fr and 6Fr catheter. Both catheters have a fixation hub and an extravascular extension line. The catheters are marked every centimeter from the hub to the proximal tip. The fixation hub is marked with the catheter French size,

K062425

and the extension lines are marked with the gauge size. A clamp is attached to each extension line, and is marked with the priming volume.

Intended Use: The Vygon LIFECATH S PICC and Midline catheters are intended for use in patients who require mid-long term IV therapy. It may be used to administer hyperalimentation antibiotics, chemotherapy, drugs for pain management or intravenous fluid.

Technology Characteristics: The Lifecath S PICC and Midline catheters are composed of silicone and substantially equivalent to the predicate devices.

Summary of Design Control Activities:

Biocompatibility data demonstrates that the materials used are non-irritant and non-toxic. Performance testing demonstrates that the device is substantially equivalent to the predicate devices. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: Biocompatibility testing, performance testing and risk assessment demonstrate that the Lifecath S is substantially equivalent to the predicate devices, and safe and effective to use, when used in accordance with the supplied instructions for use.

Courtney Smith 8/14/06

Courtney Smith Date
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP 15 2006

Re: K062425
Trade/Device Name: Lifecath S PICC and Midline Catheter
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 17, 2006
Received: August 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.

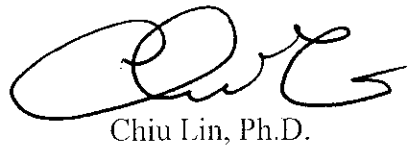
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K062425

Device Name: Lifecath S PICC AND MIDLINE CATHETER

Indications For Use:

The Vygon LIFECATH S PICC and Midline catheters are intended for use in patients who require mid-long term IV therapy. It may be used to administer hyperalimentation antibiotics, chemotherapy, drugs for pain management or intravenous fluid.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 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)

...n Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...Number: K062425