K070705

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VYGON CORPORATION
2495 General Armistead Avenue
Norristown, PA 19403-3685

(800) 544-4907
(610) 630-3350
Fax (610) 630-3835
http://www.vygonusa.com

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

Date of Preparation: March 7, 2007

Applicant:	Vygon Corporation 2495 General Armistead Ave. Norristown, PA 19403
Contact Individual:	Courtney Smith, Regulatory Affairs Manager 610-539-9300 Ext. 110
Trade Name:	Latex-free Bionector
Common Name:	Bionector
Regulation Number:	880.5200
Product Code:	FOZ
Classification Name:	Catheter, Intravascular, Therapeutic, Short-term, less than 30-days
Classification:	Class II
Predicate Device Name:	Latex Free Bionector (K052881)
Device Description:	The Latex-free Bionector is a multi-purpose, closed, needle-free IV connector to be used for the purpose of sampling, injection, or continuous infusion of fluids or drugs. The Latex-free Bionector has a disinfectable membrane (disinfection must be carried out before and after use) which closes automatically when the infusion line or the syringe is disconnected.

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Intended Use: LATEX-FREE BIONECTOR is a multi-purpose catheter accessory; a closed needle-less system permitting blood sampling, intermittent injection or continuous infusion of fluids or medications. Connection is exclusively with the Luer system. Latex-free Bionector is a Male/Female Luer, neutral displacement device. It does not displace fluid upon either connection or disconnection. Latex-free Bionector may be flushed with saline only or heparinized saline, in accordance with hospital protocol. The Latex-free Bionector is MR Conditional.

Technology Characteristics: The Latex-free Bionector is 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 Latex-free Bionector 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 11/30/07

Courtney Smith Date

Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K070705
Trade/Device Name: Latex-Free Bionector
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 26, 2007
Received: November 27, 2007

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): K070705

Device Name: Latex-free Bionector

Indications For Use:

LATEX-FREE BIONECTOR is a multi-purpose catheter accessory; a closed needle-less system permitting blood sampling, intermittent injection or continuous infusion of fluids or medications. Connection is exclusively with the Male/Female Luer system which does not displace fluid upon either connection or disconnection.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

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

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