MAR 2 2006

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

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(610) 630-3350
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510K Premarket Notification Submission
Summary of Safety and Efficacy

Date of Preparation: February 27, 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:	Vygon 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:	Vygon Bionector (K941678)

Device Description: The Latex Free Bionector is a multi-purpose, closed, needle-free IV connection accessory for sampling, injection or continuous infusion of fluids or drugs.

Intended Use: Latex Free Bionector is a multi-purpose catheter accessory; a closed needleless 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 device that displaces a positive bolus during disconnection of the Male Luer devices connected to it.

Technology Characteristics: The Bionector has a disinfectable membrane which closes automatically when the infusion line or the syringe is disconnected. The Bionector is resistant to lipid emulsions, most cytotoxic drugs and antiseptics. The Latex free is substantially equivalent to the predicate device (Bionector K941678) except that it does not contain latex.

Summary of Design Control Activities:
Biocompatibility testing of the Latex Free Bionector demonstrate that it is non-irritant and non-toxic. Performance testing demonstrates that the change in material does not affect device functionality. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: Only change between the predicate device (Bionector K941678) and the Latex Free Bionector is the change in material. Biocompatibility testing, performance testing and risk assessment demonstrate that the Latex Free Bionector 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

MAR 2 2006

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

Re: K052881
Trade/Device Name: Latex Free Bionector
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: January 31, 2006
Received: February 6, 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.

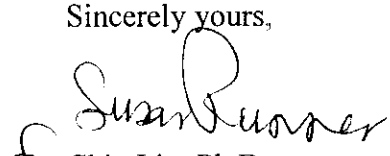
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K052881

Indications for Use

510(k) Number (if known): K052881

Device Name: Latex Free Bionector

Indications For Use:

- Latex Free Bionector is a multi-purpose catheter accessory; a closed needleless 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 device that displaces a positive bolus during disconnection of the Male Luer devices connected to it.

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)

Susan Runner

...General Hospital, ...Dental Devices

K052881