510(k) Summary of Safety and Effectiveness
LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter

Date Summary Was Prepared:	August 30, 2002
Submitter's Information:	Horizon Medical Products, Inc. One Horizon Way Manchester, GA 31816
Telephone Number:	(706) 846-3126
Fax Number:	(706) 846-5303
Contact:	Scott Moeller, RAC, Director of Quality Assurance and Regulatory Affairs
Device Trade Name:	LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter
Device Common Name:	Hemodialysis Catheter, Implanted
Classification:	78 MSD
Classification Panel :	Gastroenterology/Urology
C.F.R. Section:	876.5540
Predicate Device:	K011916 Super C™ (LifeJet™) Hemodialysis/Apheresis Chronic Catheter

DEC 13 2002

Device Description:

The LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter is a radiopaque dual lumen polyurethane catheter intended to remove and return blood. The two lumens are designed in a Circle Crescent (Circle "C") configuration. The distal venous lumen extends beyond the arterial lumen to reduce recirculation.

The lumens are connected to the extensions via a molded hub with suture wing. The arterial and venous extensions are identified by red and blue luer connectors and clamps. Priming volume information is printed on identification rings on the clamps for ease in identification. The fixed retention cuff on the shaft provides an anchoring site for tissue ingrowth during long-term placement.

The LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter is available in varied implantable lengths, with straight or J-Cannula versions.

Intended Use:

The LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter is indicated for use in attaining short and long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein. The catheter is intended for implantation dwell time of greater than 30 days.

Technological Characteristics:

The technological characteristics of the LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter, including intended use, material type, design, operating principle, performance, and method of sterilization are substantially equivalent to the Super C™ (LifeJet™) Hemodialysis/Apheresis Chronic Catheter.

The LifeJet™ modifications include:

- Change in catheter material durometer
- Increase in French size
- Dimensional specifications

The intended use, fundamental scientific technology, principle operation and basic design remain unchanged.

Performance Data:

In-vitro performance data for the modified LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter includes:

- Tensile strength
- Catheter Pressurization/Leak Testing
- Flow rate
- Catheter stiffness

Clinical data was deemed not necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to the legally marketed predicate device intended for hemodialysis and apheresis treatments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott Moeller, RAC
Director of Quality Assurance
and Regulatory Affairs
Horizon Medical Products, Inc.
One Horizon Way
MANCHESTER GA 31816

DEC 13 2002

Re: K022905
Trade/Device Name: LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter; 16F x 36cm, F16-36 Series; 16F x 40cm, F16-40 Series; 16F x 45cm, F16-45 Series; 16F x 36cm Precurved, F16-36CK Series; and 16F x 40cm Precurved, F16-40CK Series
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: August 30, 2002
Received: September 3, 2002

Dear Mr. Moeller:

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. 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"(21 CFR 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,

for Colin M. Pollard

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022905

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter

Indications for Use:

The LifeJet™ F16 Hemodialysis/Apheresis Chronic Catheter is indicated for use in attaining short and long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein. The catheter is intended for implantation dwell time of greater than 30 days.

(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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022905

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)