Premarket Notification 510(k)
(New Device)

MAY 13 2008

AngioDynamics, Inc.
DuraMax™ Hemodialysis Catheter and Procedure Kit

General Information:

ANGIODYNAMICS, Inc. intends to introduce the following device into commercial distribution:

a)	**Trade Name:**	AngioDynamics, Inc. DuraMax™ Hemodialysis Catheter and Procedure Kit
b)	**Common Name:**	Long Term Hemodialysis Catheter
c)	**Classification Name:**	Hemodialysis Catheter, Implanted
d)	**Manufacturing Site Address:**	ANGIODYNAMICS, Inc. 603 Queensbury Avenue Queensbury, New York 12804
e)	**Manufacturing Establishment Registration Number:**	1319211
f)	**Sterilization Site Address:**	Sterigenics 84 Park Rd. Glens Falls, NY 12801
g)	**Sterilizer Establishment Registration Number**	13196189
h)	**Classification:**	Hemodialysis Catheter, Implanted Product Code: 78 MSD 21 CFR 876.5540 Device Class: Class III

i) **Device Equivalence:**

This product is substantially equivalent to the following devices:

- Ash Access Ash Advance Hemodialysis Catheter and Procedure Kit, K070572
- MedComp Hemo-Flow Double Lumen Catheter, K994105, 24 – 40 cm lengths
- MedComp Hemo-Flow Double Lumen Catheter 55 cm, K030502, 55 cm in length for femoral placement

This device does not present additional risks to patients or different considerations regarding safety and effectiveness than those presented by the predicate devices.

j) **Performance Standards:** None Established

k) **ANGIODYNAMICS® Contact Information:**

Name: Teri Juckett, Regulatory Affairs Manager

Address: 603 Queensbury Avenue
Queensbury, New York 12804

Phone: (518) 798-1215 extension 1142

Fax: (518) 798-3625

Email: tjuckett@angiodynamics.com

l) **Payment Identification Number:** MD6033959-956733

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

Ms. Teri Juckett
Regulatory Affairs Manager
ANGIODYNAMICS, Inc.
603 Queensbury Avenue
QUEENSBURY NY 12804

Re: K080400
Trade/Device Name: AngioDynamics, Inc. DuraMax™ Hemodialysis Catheter and Procedure Kit
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: February 12, 2008
Received: February 13, 2008

Dear Ms. Juckett:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of 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 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, 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 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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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,

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

Enclosure

K080400

INDICATIONS FOR USE

510(k) Application: New Application

Device Name:

AngioDynamics, Inc. DuraMax™ Hemodialysis Catheter and Procedure Kit

Indications for Use:

The AngioDynamics, Inc. DuraMax™ Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis.

It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.

Alternative insertion sites include the subclavian vein as required.

Catheters greater than 40cm are intended for femoral vein insertion.

This catheter is indicated for > 30 days long-term placement.

Prescription Use ___X___ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

K080400

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number _____