OCT 20 2010

5. 510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92

Submitter:
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Date Summary was Prepared: 30-Jun-2010

Trade Name: DuraMax® Chronic Hemodialysis Catheter and Procedure Kit
Common Name: Hemodialysis Catheter
Classification Name: Catheter, Hemodialysis, Implanted
21 CFR 876.5540
Product Code MSD

Predicate Device(s): The DuraMax® Chronic Hemodialysis Catheter and Procedure Kit is substantially equivalent to the following devices:

Device Name	Manufacturer	510(k) No.
AngioDynamics® DuraMax® Catheter Kits	AngioDynamics®	K080400, cleared 5/13/08
AngioDynamics® EvenMore® Chronic Hemodialysis Catheter	AngioDynamics®	K040402, cleared 4/19/2004

Device Description:
The DuraMax® Chronic Hemodialysis Catheter and Procedure Kit is used to remove and return blood during Hemodialysis and aphaeresis. The catheter lumens are open at the distal tip and have a total of 4 side holes (two at venous tip, two at arterial tip). The distal venous tip extends beyond the arterial lumen and is tapered and curved to facilitate placement into vasculature. The distal tip also includes a guidewire lumen to facilitate insertion.

The proximal section of the device contains a fixed cuff that allows for tissue in growth for long term placement, an integrated bifurcation hub, suture wing, and extension leg set with color-coded occlusion clamps and luer connectors (red and blue for the arterial and venous lumens respectively). The lumen priming volumes are printed on the clamps. The catheter is packaged individually or as a basic kit that includes the necessary accessories to correctly insert the catheter.

Statement of Intended Use:

The Intended Use of the device described in this 510(k) is identical to the Intended Use of the predicate, DuraMax HemoDialysis Catheter and Procedure Kit, that was cleared via K080400. Specifically;

The AngioDynamics, Inc. DuraMax™ Chronic Hemodialysis Catheter is intended 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.

Substantial Equivalence:

The DuraMax® Chronic Hemodialysis Catheter and Procedure Kit has the same technological characteristics as the predicate devices that were cleared via K080400 and K040402 respectively.

Discussion of Nonclinical Tests:

The safety and performance of the DuraMax® Chronic Hemodialysis Catheter and Procedure Kit have been substantiated through extensive non-clinical testing including shaft tensile strength, joint strength, leakage, flow rate, and kit component compatibility.

Results of testing show that the DuraMax® Chronic Hemodialysis Catheter and Procedure Kit can reliably perform as a conventional hemodialysis catheter for obtaining blood access for hemodialysis and apheresis. No new questions of safety or effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. David A. Greer
Sr. Regulatory Affairs Professional
AngioDynamics, Inc.
14 Plaza Drive
LATHAM NY 12110

OCT 20 2010

Re: K101843
Trade/Device Name: DuraMax® Chronic 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: September 29, 2010
Received: September 30, 2010

Dear Mr. Greer:

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 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 and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): New Application

OCT 2 0 2010

Device Name:

DuraMax® Chronic Hemodialysis Catheter and Procedure Kit

Indications for Use:

The AngioDynamics, Inc. DuraMax™ Chronic 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 ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 Reproductive, Abdominal and Radiological Devices
510(k) Number K101843