

**5. 510(k) Summary**

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

**Date Summary was Prepared**

November 4, 2011

**Submitter**

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**FDA Establishment Registration Number**

3007282893

**Contact**

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**Device Information**

Trade Name:	Aspire MAX Aspiration Catheter
Common Name:	Embolectomy or aspiration catheter and piston syringe
Classification Name:	Embolectomy catheter
Product Code:	DXE
Regulation:	Class II, 21 CFR 870.5150

**Predicate Devices**

Aspire Max Aspiration Catheters are substantially equivalent to the Medtronic Export Aspiration Catheters, Vascular Solutions Pronto Extraction Catheters, Lumen – Volcano Xtract Aspiration Catheters, and other predicate devices.

Trade Names:	Export XT Aspiration Catheters K061958 September 5, 2006 Pronto Short Aspiration Catheter K051193 August 8, 2005 Pronto V3 Aspiration Catheter K063371 Mar 30, 2009 Xtract Aspiration Catheters K071529 August 10, 2007 Xtract Aspiration Catheter K080901 October 2, 2008
Common Name:	Embolectomy or aspiration catheter and piston syringe
Classification Name:	Embolectomy catheter
Product Code:	DXE
Regulation:	Class II, 21 CFR 870.5150

**Device Description**

Aspire MAX 5 Aspiration Catheter (MAX 5 Aspiration Catheter and Aspire Aspirator)  
Aspire MAX 6 Aspiration Catheter (MAX 6 Aspiration Catheter and Aspire Aspirator)  
Aspire Aspirator 30ml

An Aspire MAX Aspiration Catheter includes (1) Aspire MAX 5 or MAX 6 Aspiration Catheter and (1) Aspire Aspirator 30ml. Aspire MAX Aspiration Catheters and MAX Aspiration Catheters are single-use, sterile, short-term use, and non-pyrogenic medical devices designed for use with manually operated piston syringes to remove fresh, soft emboli and thrombi from the peripheral and coronary vasculature. The Aspire MAX Aspiration Catheter operating and scientific principle is the same as predicate devices. The catheter is inserted into the body over a guidewire and through a sheath or guide catheter to the target anatomy. A piston syringe is then connected to the catheter and the aspiration is manually created with the piston syringe.

Similar to predicate devices, industry standard intravascular catheter components and materials are used:

- Clear proximal polycarbonate female luer lock,
- Stainless steel braid,
- Clear Pebax and Vestamid Shafts,
- Embedded platinum iridium radiopaque marker,
- Clear polycarbonate barrel piston syringe.

Aspire MAX Aspiration Catheters do not add any new materials, manufacturing processes, colorants, or dyes to the manufacturing process.

Same as predicates, all MAX Aspiration Catheters may be may be connected to piston syringes including the Aspire Aspirator. Aspire Aspirators may be connected to other aspiration catheters.

**Indications, Intended Use and Contraindications**

Indication: The Aspire MAX 5 and MAX 6 Aspiration Catheters and Aspirator are indicated for the removal of fresh, soft emboli and thrombi from vessels in the peripheral vasculature.

Intended Use: Aspire MAX Aspiration Catheters are single-use devices intended for use by physician's experienced and trained in diagnostic and interventional procedures. Techniques for placement of vascular sheaths, catheters, and guidewires may be used.

Contraindications: The removal of fibrous, adherent or calcified material (e.g., chronic clot and atherosclerotic plaque), neurovascular use, and vessels <2.0mm diameter for the Aspire MAX 5 Aspiration Catheter and <2.5mm diameter for the Aspire MAX 6 Aspiration Catheter.

The indication and intended use is substantially equivalent other thrombus aspiration catheters manually actuated by syringes and legally marketed under the DXE product code.

**Comparison to Predicate Devices**

Aspire MAX Aspiration Catheters and Aspire Aspirator are substantially equivalent to predicate catheters used to remove fresh, soft thrombi/emboli. Substantial equivalence is based on equivalence in:

<b>Science</b>	
Scientific Principle	Mechanism of Use
<b>Device Construction</b>	
Design & Dimensions	Manual Use
Function	Piston Syringe Driven Aspiration
Materials	Manufacturing
<b>Device Performance</b>	
Aspiration	Bend & Torque
Break strength integrity	Tracking
Freedom of Leakage Injection	Freedom from Leakage Aspiration
<b>Labeling</b>	
Indication for Use & Intended Use	Contraindications
Warnings	Instructions for Use
<b>Manufacturing</b>	
ISO 10993 Biocompatibility	Sterilization

**New device is compared to predicate device?** Yes, the Aspire MAX Aspiration Catheter is compared to the predicates against predetermined metrics and performance test criteria.

**Does the new device have the same indication for use as predicate device?** Yes.

**Do the differences between the new device and predicate alter the intended therapeutic or diagnostic effect as predicate device?** No, the differences between the Aspire MAX Aspiration Catheter and predicates do not alter the intended use of the device.

**Does the new device have the same technical characteristics, materials, manufacturing processes as predicate?** Yes, the Aspire MAX Aspiration Catheter's manually operated aspiration principle of operation and technical characteristics are the same as predicates. Aspire MAX Aspiration Catheters and piston syringe materials including but not limited to Pebax and Vestamid shafts; 304 stainless steel wire braiding; luer lock hubs; and polycarbonate piston syringe barrels the same as predicates. Manufacturing extrusion, molding, and assembly in ISO 14644 Class 8 certified clean room is the same as predicates. No new materials or manufacturing processes.

**Could the new characteristics affect safety?** No.

**Do new characteristics raise new types of safety and effectiveness questions?** No.

**Do accepted scientific methods exist for assessing effects of new characteristics?** Yes, testing was based on FDA recognized standards and guidance including but not limited to:

- ISO 10555-1:1997 Sterile, Single-Use, Intravascular Catheters.

- ISO 7886-1:1993(E) Sterile Hypodermic Syringes for Single Use.
- AAMI/ANSI/ISO 11135:1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization.
- ISO 10993 Biological Evaluation of Medical Devices.
- FDA’s Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Device, May 1, 1995 (G95-1),” U.S. Food and Drug Administration, Center for Devices and Radiological Health, May 1995, attachment C Biocompatibility Flow Chart for the Selection of Toxicity Test for 510(k)s.

### **Non-Clinical Testing**

Non-clinical testing confirms the Aspire MAX Aspiration Catheters and Aspirator passes all testing and meets specifications. Specific tests confirm functionality in the intended use, safety, demonstration of claims, and equivalence to predicate devices plus compliance with ISO recognized standards.

#### **A. General:**

- Mold validation,
- Visual inspection pre-packaging,
- Package sealer validation,
- Tyvek seal test,
- Packaging and shipping test,
- Packaging visual appearance,
- Label integrity and legibility,

#### **B. Integrity and compatibility:**

- Particulate testing,
- Catheter corrosion resistance,
- Catheter body tensile strength integrity,
- Catheter body to hub tensile strength integrity,
- Catheter tip attachment strength,
- Catheter leakage at hub integrity positive pressure,
- Catheter leakage at hub integrity vacuum,
- Catheter vacuum collapse integrity,
- Catheter tracking test,
- Catheter torque,
- Catheter kink resistance,
- Catheter radiopaque visibility,
- Guidewire interface,
- Guidecath interface,
- Sheath interface,
- Pulsed aspiration integrity tests,
- Aspiration fatigue integrity,

#### **C. Aspiration:**

- MAX Aspiration Catheters and predicates with standard syringes and aspirators with low viscosity aspirants,
- MAX Aspiration Catheters and predicates with standard syringes and aspirators with high viscosity Newtonian aspirants,

- MAX Aspiration Catheters and predicates with standard syringes and aspirators with high viscosity Non-Newtonian aspirants,
  - Thrombus aspiration,
  - In-vivo aspiration.
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- Biocompatibility: Compliance with “Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Device, May 1, 1995 (G95-1),” U.S. Food and Drug Administration, Center for Devices and Radiological Health, May 1995, attachment C Biocompatibility Flow Chart for the Selection of Toxicity Test for 510(k)s and ISO 10993. Subject devices passed all biocompatible tests performed by Ethox and Nelson Labs.
  - Particulate testing include validated light obscuration method and direct visualization tests. Subject devices passed with scores significantly below an established minimum national standard.

**Clinical testing**

Not applicable.

**Statement of Equivalence**

Aspire MAX Aspiration Catheters are substantially equivalent to the currently marketed Pronto, Export, and Xtract aspiration systems based on comparison of the device classification, basic operating principle, indication for use, intended use, technical characteristics, packaging, and sterilization methods.

**Conclusion**

Aspire MAX Aspiration Catheters are substantially equivalent to the currently marketed Pronto, Export, and Xtract catheters based on comparison of the device classification, basic operating principle, indication for use, intended use, technical characteristics, packaging, and sterilization methods. Testing confirms the suitability of Aspire MAX Aspiration Catheters and Aspirator for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

FEB 22 2012

Control Medical Technology  
c/o Mark Job  
Responsible Third Party Official  
Regulatory Technical Services LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 55313

Re: K113757

Trade/Device Name: Aspire MAX Aspiration Catheters (MAX 5 and MAX 6)  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: DXE  
Dated: December 20, 2011  
Received: December 21, 2011

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

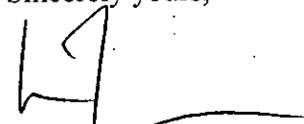
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**4. Indication for Use Statement**

510(k) Number:     K113757    

Device Name:       Aspire MAX Aspiration Catheter

Indications for Use:

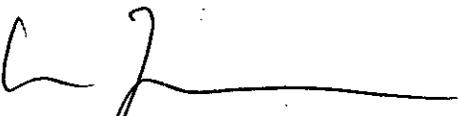
The Aspire MAX 5 and MAX 6 Aspiration Catheters and Aspirator are indicated for the removal of fresh, soft emboli and thrombi from vessels in the peripheral vasculature.

Prescription Use                       AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use   
(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number     K113757