Section 5- 510(k) Summary

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Date Prepared: September 27, 2011

Trade Name: St Jude Medical Agilis™ PF Introducer System and accessories

Classification: Class II – 21 CFR 870.1340
Catheter Introducer

Product Code: DYB

Predicate Device: The subject device is equivalent to the following St Jude Medical Device

St Jude Medical Agilis NxT Steerable Introducer - G402049 and 17 Gauge Tuohy Needle

St. Jude Medical Fast Cath Introducer (Predicate Device – 13F Obturator)

Device Description: The St. Jude Medical Agilis™ PF Introducer System consisting of a introducer, guidewire, 17Ga Tuohy needle, dilator and obturator is intended to be used to facilitate delivery of SJM devices into the pericardial space for diagnostic and therapeutic purposes

Intended Use: The Agilis™ PF Introducer System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies.

Comparison to Predicate Devices: The St Jude Medical Agilis™ PF Introducer system has a similar intended use and the same fundamental scientific technology as the predicate device. All technological characteristics of the Agilis™ PF Introducer system are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Where
differences exist between the proposed device and the predicate device. Performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device.

Conclusion: St Jude Medical considers the Agilis™ PF Introducer system to be equivalent to the predicate device listed above. This conclusion is based upon the device similarities in design, technological characteristics, principles of operation, materials and indications for use.
Introduction

The following Instructions for Use describe the contents of the St. Jude Medical Agilis™ PF Introducer System and their application in accessing the pericardial space. Please read these instructions thoroughly before using the Agilis PF Introducer System or any of its components to help reduce the potential risks and complications associated with surgical procedures.

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Agilis™ PF Introducer System

Description

The Agilis™ PF Introducer System consists of the following components:
- Deflectable introducer, 13 French
- Dilator
- Guidewire
- Obturator
- 17Gx Tuohy Needle

The deflectable introducer is fitted with a hemostasis valve to minimize air introduction during introducer insertion and/or exchange. A sideport with a three-way stopcock is provided for air or blood aspiration and fluid infusion. A needle equipped with a deflection control mechanism deflects the tip up to 90° both clockwise and counterclockwise. The introducer features a radiopaque tip marker to improve fluoroscopic visualization.

Indications

The Agilis™ PF Introducer System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate percutaneous interventions.

Contraindications
- Congenital absence of the pericardium
- Absence of a free pericardial space

Warnings
- Do not alter the introducer system in any way.
- Single-use disposable medical device. Do not reuse.
- Ensure the patient's hemodynamic parameters are acceptable prior to advancing the dilator or any other component. Continue hemodynamic monitoring throughout the procedure.
- Perform operations such as aspiration, component removal, and introducer exchanges slowly to minimize the potential for creating a vacuum in the introducer.
- Hypercoagulable conditions/anticoagulation should not be present or given until pericardial access has been obtained.
- Only those physicians who are specially trained in subxiphoid access should use this introducer system.
- During insertion, avoid creating excessive bends in the introducer or other components.
- Use fluoroscopy to verify the position of the introducer and other components and to assist guiding the devices through the patient's anatomy.

Precautions
- Inspect all components before use. Do not use if the package or items in the kit appear to be damaged or defective.
- Contents are sterile if package is unopened and undamaged.
- The French size specified on the dilator and obturator hubs indicates the outer diameter of these components. This should match the French size of the Agilis™ PF Introducer (as specified on the hub). Do not attempt to insert into the introducer any device that has a distal tip or body size larger than the introducer size indicated.
- Ensure that the notch on needle stylet and the corresponding slot on the needle hub face upwards during insertion. This helps ensure that the needle tip is curved in the upwards direction during insertion. This in turn reduces the risk of accidental myocardial perforation/catheterization during needle insertion.
Do not attempt to use a guide wire larger than the maximum diameter specified on the package label.

Prior to inserting the introducer into the patient, pre-assemble the detachable introducer and dilator.

The Agilis PF introducer hemostasis valve cap is designed to interlock only with the supplied dilators and obturators. Misuse may result in complications.

Do not remove dilator or introducer rapidly. Damage to the backbead valve may occur.

Do not deflect the introducer when the dilator has been inserted.

If resistance is met when advancing or withdrawing the guidewire or introducer, determine the cause and correct the problem before continuing with this procedure.

Avoid aspiration and fluid infusion (such as saline flush) should be carried out only through the sheath.

This system should only be used with equipment that complies with international safety standards.

Always straighten the introducer tip before inserting or removing the introducer from the patient. Prior to removing the introducer, verify that the tip is straight by viewing the tip on fluoroscopy.

Dispose of this introducer system according to standard hospital procedures.

Individual patient anatomy and physician technique may require procedural variations.

Do not use the introducer as an abdominal cavity puncture tool.

Aspiration and fluid infusion (such as saline flush) should be carried out only through the sheath.

This system should only be used with equipment that complies with international safety standards.

Always straighten the introducer tip before inserting or removing this introducer from the patient. Prior to removing the introducer, verify that the tip is straight by viewing the tip on fluoroscopy.

Dispose of this introducer system according to standard hospital procedures.

Individual patient anatomy and physician technique may require procedural variations.

Store in a cool, dry, dark place.

Potential Complications

As with any catheterization procedure, potential complications include but are not limited to:

- Thromboembolism
- Air embolism
- Local and systemic infection
- Bleeding or hematoma at puncture site
- Perforation (e.g., diaphragm, liver, lung and vessels)
- Thrombus formation
- Epicardial irritation
- Perforation of the heart chambers leading to cardiac tamponade
- Pericarditis
- Hemopericardium
- Esophageal injury
- Coronary artery injury
- Abdominal bleeding
- Pneumopericardium
- Atrial fibrillation (AF)
- Ventricular tachycardia (VT) requiring cardioversion
- Ventricular fibrillation (VF)
- Myocardial infarction

How Supplied

The St. Jude Medical Agilis™ PF Introducer System is supplied sterile, for single use only, provided the package is unopened and undamaged.

Recommended Patient Screening

Patients with the following pre-existing conditions may not be suitable for this procedure:

- Congenital absence of the pericardium
- Epicardial surface fat pad on the epicardium surface >5 mm
- Constrictive and adhesive pericarditis (large percentage of adhesion)
- Active infection

Note

Ensure that the patient has been appropriately treated for infections and does not have any active infections, prior to undergoing this procedure.

- Previous cardiac surgery
- Myocardial infarction

Note

These pre-existing conditions may inhibit access to areas of the epicardium due to pericardial fibrosis. Special care should be used when performing pericardial access procedures in these patients.

- Hemodynamic instability
- Unsuitable angina

Agilis™ PF Introducer System
Sep 27, 2011

- Recent cerebral vascular accident (CVA)
- Presence of acute cardiac thrombus
- Acute conditions, such as electrolyte abnormality, acute ischemia, and drug toxicity
- Gastrointestinal perforation

Procedural Considerations

The following are among the procedural considerations that should be examined prior to use of the introducer system. They are designed to better prepare the clinician for potential complications associated with the subxiphoid technique and pericardial anatomy in general, such as air embolism.

- Prior to catheterization, the patient’s clotting system should be evaluated. Use anticoagulant as training and experience may dictate.
- Subxiphoid procedures should be performed only in facilities appropriately equipped and staffed to perform such procedures. Laboratory capabilities should include, but are not limited to:
  - Intracardiac pressure monitoring
  - Systemic pressure monitoring
  - Pericardiotensis
  - Surgical backup
  - Appropriate monitoring of vital signs throughout the procedure
  - Familiarity with contrast media injection and management of untoward reactions to contrast media.

Note

Excessive contrast may reduce visibility under fluoroscopy.

Pericardial Access

Use the Agili™ PF Introducer system to gain access to the pericardial space with a subxiphoid procedure. This serves as a conduit during delivery of St. Jude Medical devices.

Use fluoroscopic guidance to gain access to the pericardial space.

1. Create a subxiphoid incision that sufficiently allows introducer access and maneuverability.
2. Use the Tuohy needle to gain access to the pericardial space. First, the needle should be placed at the level of the diaphragm 1 to 2 cm posterior to the pectoralis major muscle. Then, inject a small amount of contrast material to confirm needle position and inject small amount of contrast.
3. Insert the guidewire into the Tuohy needle.
4. Advance the guidewire into the pericardial space. Proceed with the introducer, into the pericardial space in a forward manner using a fluoroscopic left lateral view of the introducer handle.
5. Remove the Tuohy needle while retaining the guidewire in place.
6. Flush the introducer and the dilator with sterile saline.
7. If the introducer tip is already deflected, use the deflection control mechanism to straighten the tip. This mechanism is located on the introducer handle.
8. Insert the dilator into the introducer and lock the dilator into the hemostasis cap.
9. Place the dilator over the guidewire. Advance the introducer and dilator into the pericardial space.
10. Remove the dilator and guidewire from the introducer.
11. Insert the obturator into the introducer and lock the obturator into the hemostasis cap.
12. With the obturator in place, maneuver the introducer and deflect the introducer tip to access the desired location.
13. Remove the obturator and if required, carefully adjust the introducer position for subsequent cardiac diagnostic and/or therapeutic device delivery.
14. Always straighten the introducer tip before removing the introducer from the patient. When the device is inside the patient, verify the tip position using fluoroscopy prior to removing the introducer system.

Note

If required, remove air by closing the hemostasis valve and withdrawing air through the three-way stopcock.

Available Accessories

Additional accessories available for use with the St. Jude Medical Agili™ PF Introducer System include:

- Agili™ PF Introducer Accessory Kit 18G, 300-cm guidewire, 13Fr. (Dilator, 13Fr. Obturator and 17Ga. Tuohy needles)
Symbols

Store in a cool, dark, dry place

Sterile, sterilized using ethylene oxide

Do not reuse

Consult instructions for use

Use by

Do not use if package is damaged

Manufacturer

Manufacturing date

Authorized representative in the European Community

Temperature limitations

Prescription only

Diameter

Inner diameter

Outer diameter

Inner and outer diameters
St. Jude Medical, CRM  
c/o Ms. Geena George  
Associate Regulatory Submission Specialist  
15900 Valley View Court  
Sylmar, CA 91342  

Re: K111943  
Trade/Device Name: Agilis™ PF Introducer System  
Regulatory Number: 21 CFR 870.1340  
Regulation Name: Catheter introducer  
Regulatory Class: II (two)  
Product Code: 74 DYB  
Dated: September 19, 2011  
Received: September 20, 2011  

Dear Ms. George:  

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 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,

[Signature]

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

Enclosure
Indications for Use

510(k) Number (if known): _K111943_

Device Name: St Jude Medical Agilis™ PF Introducer System and accessories

Indications for Use: The Agilis™ PF Introducer System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies.

Prescription Use _X_ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number _K111943_