PREMARKET NOTIFICATION [510(k)] SUMMARY

Date Prepared: January 21, 2009
Submitter: St. Jude Medical, CRMD
Address: 15900 Valley View Court
Sylmar, CA 91324
Phone: 818 493-2629
Fax: 818 493-3615
Contact Person: Geena George
Trade Name/Proprietary Name: SJM Stylet Model Numbers:
4060, 4062, 4064
4090, 4091
4078
Locator Plus
S-60-S, S-60-X, S-60-F
S-65-S, S-65-F, S-65-X
S-75-X, S-75-S, S-75-F
S-60-XS, S-65-XS, S-75-XS

Common Name: Stylet
Classification: Class II, 21 CFR 870.1380

Legally marketed device to which your firm is claiming equivalence: St. Jude Medical stylets under review are all currently commercially available.

<table>
<thead>
<tr>
<th>SJM Stylet Model</th>
<th>Approved with PMA Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>4060, 4062 and 4064</td>
<td>P960030/S10</td>
</tr>
<tr>
<td>4090 and 4091</td>
<td>P960013/S15</td>
</tr>
<tr>
<td>Locator Plus</td>
<td>P960013/S022</td>
</tr>
<tr>
<td>S-60-S, S-60-X, S-60-F</td>
<td>P950022/S16</td>
</tr>
<tr>
<td>S-65-S, S-65-F, S-65-X</td>
<td>P950022/S14, P950022/S16</td>
</tr>
<tr>
<td>S-75-X, S-75-S, S-75-F</td>
<td>P950022/S17</td>
</tr>
<tr>
<td>S-60-XS, S-65-XS, S-75-XS</td>
<td>P950022/S34</td>
</tr>
</tbody>
</table>
1) Stylet Model 4060, 4062 and 4064

A. Device Description
The Stylet models 4060, 4062, 4064 were reviewed and approved by FDA with the Isoflex S family of leads under P960030/S10 on April 10, 2003. Stylet lengths approved were 34cm, 40cm, 46cm, 52cm, 58cm, 85cm.
Model 4060 is a soft straight stylet 0.35mm (.014") with green knob.
Model 4062 is a firm straight stylet 0.38mm (0.015") with yellow knob.
Model 4064 is an extra firm straight stylet 0.41mm (0.016") with red knob.

The market released Isoflex S specification sheet referencing the stylet models is included as appendix 1
The stylet models 4060, 4062 and 4064 are intended for use in the placement of Isoflex S passive fixation pacing leads. The Isoflex S lead is designed for use to provide permanent pacing and sensing in either the atrium or ventricle.

4060 stylet accessories kit contains:
Two 0.014” stainless steel stylets with button I.D. designating the length of the stylet:
• 2 Soft stylets with green knob and green button.

4062 stylet accessories kit contains:
Two 0.015” stainless steel stylets with button I.D. designating the length of the stylet:
• 2 Firm stylets with yellow knob and yellow button

4064 stylet accessories kit contains:
Two 0.016” stainless steel stylets with button I.D. designating the length of the stylet:
• 2 X–Firm stylets with red knob and red button

A stylet ring is used to hold the stylets. The kits shall be packaged in double trays or in double pouches.
These stylets are available with leads and also as accessories with packaging identical to the packaging under PMA P960030/ S10.

Stylet Testing
Stylet insertion/extraction testing was performed with Isoflex S family of leads per QTR 0210866, section 8.11(attached in appendix 2) and per QTR 02109049, section 8.12 (attached in appendix 3)

Sterilization and Packaging
The stylets are held in a common polymer ring, packaged and sealed within a polymer tray documented as per QTR 1392-A (attached in appendix 4). The stylet kits are sterilized at Steris Isomedix and meets all requirements as per QTR2264 (included as appendix 5)
Shelf Life
The 4060, 4062 and 4064 stylets have a shelf life approved for 3 years for leads packaged with the stylets under PMA P960030/S10

Labeling
Labels for commercially available stylet models 4060, 4062 and 4064 is included as appendix 6

B. Indications for use
The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices
St Jude Medical believes the stylet kit models 4060, 4062 and 4064 to be substantially equivalent to the predicate stylet models 4060, 4062 and 4064 approved by FDA under the Isoflex S family of leads under P960030/S10 on April 10, 2003.
Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion
The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet models 4060, 4062 and 4064 through this 510K Pre- Market Notification.

2) Stylet Model 4090 and 4091
A. Device Description
The Stylet Accessory kit models 4090 and 4091 were reviewed and approved by FDA with the Tendril ST lead model 1788T/TC and 1782 TC under P960013/S15 on Feb 7, 2006. Stylet lengths approved were 25cm, 34cm, 40cm, 46cm, 52cm, 58cm, 65cm, 85cm and 100cm. Included in appendix 7 is the information referencing the stylets as discussed with FDA on January 20, 2006.
The stylet models 4090 and 4091 are intended for use in the placement of Tendril ST Model 1788T/TC and Model 1782 TC pacing leads.
These are stainless steel stylets with button I.D. designating the length of the stylet.
Each 4090 stylet accessories kit contains:

- 1 Fixation Tool
- 1 Clip-on Tool
- 1 J-shaped Soft (.014” wire) stylets with green knob and white button
- 1 Straight X-Soft (.014” wire) stylets with light green knob and green button
- 1 Straight Soft (.014” wire) stylets with green knob and green button.
- 1 Straight Firm (.015” wire) stylets with yellow knob and yellow button
• 1 Straight X-Firm (.016" wire) stylets with red knob and red button

Each 4091 stylet accessories kit contains

• 1 Clip-on Tool
• 1 J-shaped Soft (.014" wire) stylet with green knob and white button.
• 1 Straight X-Soft (.014" wire) stylets with light green knob and green button.
• 1 Straight Soft (.014" wire) stylets with green knob and green button.
• 1 Straight Firm (.015" wire) stylets with yellow knob and yellow button.
• 1 Straight X-Firm (.016" wire) stylets with red knob and red button.

A stylet ring is used to hold these stylets.
The 4090 kit with pre-packaged Fixation Tool and Clip-on Tool shall be packaged in double pouches. The 4091 kit with clip-on tool shall be packaged in double pouches.

Stylet Testing
Description of the stylet kit model 4090 & 4091 as well as the qualification testing on the 4090, 4091 stylets kit models was performed per QTR 1861 and had previously been submitted as part of the 1788/1782 RTR submission. This QTR 1861 is included as appendix 8.

Sterilization & Packaging
The stylets and accessory Kit 4090 and 4091 sterilization and packaging validation was performed per QTR 1861 and is included in Appendix 8.

Shelf Life
The 4090 and 4091 stylet have a shelf life approved for 3 years for leads packaged with the stylets under P960013/S15.

Labeling
Labels for commercially available stylet model 4090 and 4091 are included as appendix 9.

B. Indications for use
The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices
St Jude Medical believes the stylet kit models 4090 and 4091 to be substantially equivalent to the predicate stylet models 4090 and 4091 approved by FDA under the Tendril ST lead model 1788T/TC and 1782 TC under P960013/S15 on Feb 7, 2006. Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.
D. Conclusion
The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet kit models 4090 and 4091 through this 510K Pre-Market Notification.

3) Stylet Model 4078S
A. Device Description
Stylet kit 4078S was approved under PMA P030054/S49 with Quickflex Model 1156T and Quickflex XL Model 1158T on July 25, 2007. The Quickflex Model 1156T and Quickflex XL Model 1158T leads have applications as part of a St Jude Medical Biventricular system. Stylet lengths approved were 75cm and 86 cm.

The 4078 stylet is constructed of stainless steel. Stylet accessory kit (Model 4078S) consisting of a fully packaged and labeled set of six ball-tipped stylets.
- One Extra firm stylet with 0.025 cm (0.010”) taper (red button)
- Two Firm stylets with 0.020 cm (0.008”) taper (yellow button)
- Three Soft stylets with .015 cm (.006”) taper (green button)

A stylet ring is used to hold the stylets. The 4078 kits shall be packaged in a single pouch.

Stylet Testing
Stylet insertion/extraction testing was performed per QTR 2019 for 1156T Quickflex leads and per QTR 2020 for 1158T Quickflex leads attached in Appendix 10.

Sterilization and Packaging
The stylets kit 4078 sterilization and packaging validation was not required. Sterilization and packaging validation performed on the 4068 stylet kit per QTR 1511 is applicable and is included in appendix 11.

Shelf Life
The 4078 stylet has a shelf life approved for 3 years for leads packaged with the stylets under P030054/S49

Labeling
Labels for commercially available stylet model 4078 are included as appendix 12.

B. Indications for use
The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.
C. Substantially Equivalent Devices
St Jude Medical believes the stylet model 4078 to be substantially equivalent to
the predicate stylet model 4078 approved by FDA under PMA P030054 with
Quickflex Model 1156T and Quickflex XL Model 1158T on Feb 5, 2007.
Labeling, packaging and sterilization of the stylets is substantially equivalent to
that of the predicate stylets.

D. Conclusion
The information presented supports a determination of substantial equivalence
and therefore clearance of the SJM stylet model 4078 through this 510K Pre-
Market Notification.

4) Locator Plus Stylets
Device Description
Locator plus deflectable stylets 1281, 1282, 1283, 1291, 1292, 1293 were approved
under PMA P960013/S022 on October 10, 2006. The lengths approved are 42cm,
56cm, 65cm and 58cm.
The Locator plus RTR submission is included as appendix 13. The FDA approval
letter for the Locator plus RTR is provided in Appendix 14.
Locator plus deflectable stylet is a disposable implantation tool which facilitates
defining and varying the curvature of the distal portion of an endocardial pacing
lead, as well as controlling the lead’s helix extension and retraction during lead
insertion.
The stylet package contains
• 1 Locator® Plus Deflectable Stylet.
• 1 Protection tube with plastic stop
  attached to the tube.
• 1 Transport protection attached to the
  Stylet.
• 1 User’s Manual.

The product is double-packaged in PETG inner and outer trays
with tyvek seals to maintain sterility.

Shelf Life
The Locator plus stylet has a shelf life approved for 2 years under P960013/S022.

B. Indications for use
The locator Plus Deflectable stylet is intended for use when implanting St Jude
Medical active fixation straight endocardial pacemaker leads, Tendril® Model
1688 SDX and higher.
C. Substantially Equivalent Devices
St Jude Medical believes the Locator Plus Deflectable stylet to be substantially
equivalent to the predicate Locator Plus Deflectable stylet approved by FDA
under PMA P960013/S022 on October 10, 2006.

D. Conclusion
The information presented supports a determination of substantial equivalence
and therefore clearance of the SJM Locator Plus Deflectable stylet through this
510K Pre- Market Notification.

A. Device Description
These stylet accessory kits support the Riata Model 1500 family of leads. They
were approved under PMA P950022/S14 on March 11, 2002 and PMA
The market released leads specification sheet referencing the stylet models is
included as appendix 15.

These stylets are used with Tachyarrhythmia leads. All stylets are constructed of
304 stainless steel and a molded ABS thermoplastic hub that is colored red,
yellow, green to identify between extra firm, firm and soft. The soft stylet S-65-S
has a 0.014 inch diameter, the firm stylet S-65-F has a 0.015 inch diameter and
the extra firm stylet S-65-X has a 0.016 inch diameter.
Each S-65-S kit contains (1) clip on tool and the following stylets
  • 2 soft(0.014”wire) ball tipped, stylets with green knob
Each S-65-F kit contains (1) clip on tool and the following stylets
  • 2 firm(0.015”wire) ball tipped, stylets with yellow knob
Each S-65-X kit contains (1) clip on tool and the following stylets
  • 2 extra firm(0.016”wire) ball tipped, stylets with red knob

A stylet ring holder is used to hold the stylets. The kit shall be packaged in double
trays or in double pouches. The final sterile package shall be packaged in a poly
bag.

Stylet Testing
Stylet insertion extraction test was conducted as per Qualification Test Report
QTR1403 attached in appendix 16.

Sterilization and Packaging
These stylets are packaged with the Riata and Durata family of leads. Sterilization
and packaging validation was performed per QTR 2264 and is included in
appendix 5.
Shelf Life
These stylets have a shelf life approved for 3 years for leads packaged with the stylets under P950022/S14 and P950022/S16

Labeling
Labels for commercially available stylet model S-65-S, S-65-F, S-65-X are included as appendix 17.

B. Indications for use
The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices
St Jude Medical believes the stylet models S-65-S, S-65-F, S-65-X to be substantially equivalent to the predicate stylet model S-65-S, S-65-F, S-65-X approved by FDA under PMA P950022/S14 on March 11, 2002 and PMA P950022/S16 on March 25, 2003 with Riata Model 1500 family of leads. Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion
The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylets S-65-S, S-65-F, S-65-X through this 510K Pre-Market Notification.

6) Stylet Model S-60-S, S-60-X, S-60-F

A. Device Description
These stylet models are developed to support the Riata defibrillation lead models 1572 and 1582. They were approved under PMA P950022/S16 on March 25, 2003.

The market released lead model 1572 and model 1582 specification sheet referencing the stylet models is included as appendix 18.

These stylets are used with Tachyarythmia leads. All stylets are constructed of 304 stainless steel and a molded ABS thermoplastic hub that is colored red, yellow, and green to identify between extra firm, firm and soft. The soft stylet S-60-S has a 0.014 inch diameter, the firm stylet S-60-F has a 0.015 inch diameter and the extra firm stylet S-60-X has a 0.016 inch diameter.

Each S-60-S kit contains (1) clip on tool and the following stylets
- 2 soft(0.014"wire) ball tipped, stylets with green knob

Each S-60-F kit contains (1) clip on tool and the following stylets
- 2 firm(0.015"wire) ball tipped, stylets with yellow knob

Each S-60-X kit contains (1) clip on tool and the following stylets
- 2 extra firm(0.016"wire) ball tipped, stylets with red knob
A stylet ring holder is used to hold the stylets. The kit shall be packaged in double trays or in double pouches. The final sterile package shall be packaged in a poly bag.

**Stylet Testing**
Stylet insertion extraction test was conducted per qualification test report QTR1472 for Riate Model 1572 attached in appendix 19 and QTR1462 for Riata Model 1582 lead attached in appendix 20.

**Sterilization and Packaging.**
These stylets are packaged with the Riata and Durata family of leads. Sterilization and packaging validation was performed per QTR 2264 and is included in appendix 5.

**Shelf Life**
These stylets have a shelf life approved for 3 years for leads packaged with the stylets under P950022/S16.

**Labeling**
Labels for commercially available stylet model S-60-S, S-60-X, S-60-F are included as appendix 21.

**B. Indications for use**
The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

**C. Substantially Equivalent Devices**
St Jude Medical believes the stylet models S-60-S, S-60-F, S-60-X to be substantially equivalent to the predicate stylet model S-60-S, S-60-F, S-60-X approved by FDA under PMA P950022/S16 on March 25, 2003 with Riata defibrillation lead models 1572 and 1582.
Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

**D. Conclusion**
The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet S-60-S, S-60-F, S-60-X through this 510K Pre-Market Notification.

7) **Stylet Model S-75-X, S-75-S, S-75-F**

**A. Device Description**
Stylet Models S-75-X, S-75-S and S-75-F were approved under PMA P950022/S17 on July 1, 2003. The market released lead models 1580, 1581 and 1582 specification sheet referencing the stylet models is included as appendix 22.
These stylets are used with Tachyarrythmia leads. All stylets are constructed of 304 stainless steel and a molded ABS thermoplastic hub that is colored red, yellow, and green to identify between extra firm, firm and soft. The soft stylet S-75-S has a 0.014 inch diameter, the firm stylet S-75-F has a 0.015 inch diameter and the extra firm stylet S-75-X has a 0.016 inch diameter.

Each S-75-S kit contains (1) clip on tool and the following stylets
  - 2 soft(0.014”wire) ball tipped, stylets with green knob
Each S-75-F kit contains (1) clip on tool and the following stylets
  - 2 firm(0.015”wire) ball tipped, stylets with yellow knob
Each S-75-X kit contains (1) clip on tool and the following stylets
  - 2 extra firm(0.016”wire) ball tipped, stylets with red knob

A stylet ring holder is used to hold the stylets. The kit shall be packaged in double trays or in double pouches. The final sterile package shall be packaged in a poly bag.

**Stylet Testing**
Stylet insertion extraction test was performed and validated as per QTR 1606 for the Riata model 1580/1581 attached in appendix 23.

**Sterilization and Packaging.**
These stylets are packaged with the Riata/Durata leads. Sterilization and packaging validation was performed per QTR 2264 and is included in appendix 5.

**Shelf Life**
These stylets have a shelf life approved for 3 years for leads packaged with stylets under P950022/S17.

**Labeling**
Labels for commercially available stylet models S-75-X, S-75-S, S-75-F are included as appendix 24.

**B. Indications for use**
The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

**C. Substantially Equivalent Devices**
St Jude Medical believes the stylet models S-75-X, S-75-S, S-75-F to be substantially equivalent to the predicate stylet model S-75-X, S-75-S, S-75-F approved by FDA under PMA P950022/S17 on July 1, 2003 with Riata lead models 1580, 1581 and 1582.
Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.
D. Conclusion
The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet S-75-X, S-75-S, S-75-F through this 510K Pre-Market Notification.

8) Stylet model S-60-XS, S-65-XS, S-75-XS
A. Device Description
These stylet models were approved under PMA P950022/S34 on March 8, 2007. These stylet accessory kits include the existing extra firm, firm, soft stylets with the addition of the extra soft stylet. The extra soft stylet models (S-60-XS, S-65-XS, S-75-XS) have the same material properties as the existing soft stylets. The differences are due to the variation in the taper length and taper diameter at the tip, which provides for a more flexible or extra soft distal end. The extra soft stylets were approved under P950022/S34 on March 8, 2007. The information detailing the extra soft stylets as discussed with FDA on January 29, 2007 is included as appendix 25.

These stylets are used with Tachyarrythmia leads. The extra soft stylets are light green in color.
Each stylet kit contains (1) clip-on tool and the following stylets:
• 2 Straight X-Soft (.014” wire) ball-tipped, stylets with light green knob

A stylet ring is used to hold the stylets.
The kits with Clip-on Tool shall be packaged in double pouches.

Stylet Testing
Stylet insertion extraction test was conducted as per qualification report QTR 2041 and is attached in appendix 26.

Sterilization and Packaging
The extra soft stylets are inserted into the Riata lead when packaged. Sterilization and packaging validation performed per QTR 1392-G is included in appendix 27.

Shelf Life
These stylets have a shelf life approved for 3 years for leads packaged with stylets under P950022/S34.

Labeling
Labels for commercially available stylet model S-60-XS, S-65-XS, S-75-XS are included as appendix 28.
B. Indications for use
The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices
St Jude Medical believes the stylet models S-60-XS, S-65- XS, S-75-XS to be substantially equivalent to the predicate stylet model S-60-XS, S-65- XS, S-75-XS approved by FDA under PMA P950022/S34 on March 8, 2007. Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion
The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet S-60-XS, S-65- XS, S-75-XS through this 510K Pre- Market Notification.
St. Jude Medical  
Cardiac Rhythm Management Division  
Geena George  
Regulatory Affairs Associate  
15900 Valley View Court  
Sylmar, California  91342  

Re:  K090163  
Trade/Device Names:  
Stylet Models 4060, 4062, 4064  
Stylet Models 4090, 4091 Accessory Kit  
Stylet Model 4078  
Locator Plus Stylets 1281, 1282, 1283, 1291, 1292, 1293  
Stylet Model S-60-S, S-60-F, S-60-X  
Stylet Model S-65-S, S-65-F, S-65-X  
Stylet Model S-75-S, S-75-F, S-75-X  
Stylet Model S-60-XS, S-65-XS, S-75-XS  

Regulation Number: 21 CFR 870.1380  
Regulation Name: Catheter stylet  
Regulatory Class: Class II  
Product Code: DRB  
Dated: January 21, 2009  
Received: January 22, 2009  

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 such 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 (21 CFR Part 801), please contact the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometrics’ (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

[Signature]

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

Enclosure
STATEMENT OF INDICATIONS FOR USE

510(k) Number: K090163

Device Name: St Jude Medical Stylet Model Numbers:
- 4060, 4062, 4064
- 4090, 4091
- 4078
- Locator Plus
- S-60-S, S-60-X, S-60-F
- S-65-S, S-65-F, S-65-X
- S-75-X, S-75-S, S-75-F
- S-60-XS, S-65-XS, S-75-XS

Indications for Use: The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use

(Please do not write below this line—continue on another page of needed)

Division of Cardiovascular Devices
510(k) Number K090163