



Food and Drug Administration
10903 New Hampshire Avenue
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June 17, 2015

Baylis Medical Company Inc.
Ms. Meghal Khakhar
Director, Regulatory & Scientific Affairs
2645 Matheson Blvd. East
Mississauga, ON Canada L4W 5S4

Re: K150709

Trade/Device Name: Protrack Rf Anchor Wire
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy Catheter
Regulatory Class: Class II
Product Code: DXF
Dated: March 18, 2015
Received: March 19, 2015

Dear Ms. Khakhar:

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.

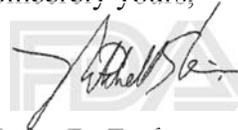
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram 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): _____

Device Name: ProTrack RF Anchor Wire

Indications for Use:

The ProTrack RF Anchor Wire is indicated for the creation of an atrial septal defect in the heart.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7. 510(k) Summary

Submitter Information

- A. *Company Name*: Baylis Medical Company Inc.
- B. *Company Address*: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada
- C. *Company Phone*: (905) 602-4875
- D. *Company Facsimile*: (905) 602-5671
- E. *Contact Person*: Meghal Khakhar
- F. *Summary Prepared on*: 18-Mar-2015

Device Identification

- A. *Device Trade Name*: ProTrack RF Anchor Wire
- B. *Device Common Name*: Septostomy catheter
- C. *Classification Name*: 21 CFR 870.5175 - Septostomy catheter
- D. *Product Code*: DXF
- E. *Device Class*: Class II

Identification of Predicate Devices

Table 1: Predicate Devices

Predicate Device	Manufacturer	510(k) No.
Nykanen Radiofrequency Wire	Baylis Medical Company Inc.	K990284
NRG Transseptal Needle	Baylis Medical Company Inc.	K073326

Indications for Use

The ProTrack RF Anchor Wire is indicated for the creation of an atrial septal defect in the heart.

Device Description

The ProTrack RF Anchor Wire is a sterile, single-use device that delivers radiofrequency (RF) power in a monopolar mode to its distal electrode. The device connects to a separately cleared Baylis Medical Company (BMC) RF Puncture Generator at its proximal end through a compatible BMC Connector Cable.

The ProTrack RF Anchor Wire is comprised of a core stainless steel wire. The body of the wire is coated with an insulating material to facilitate smooth advancement of the device and to provide electrical insulation. The wire's distal end is atraumatic and curved to prevent the wire from slipping back into the right atrium through the atrial septal defect when devices are being retracted or advanced over it. A marker coil is positioned on the distal curve for visualization under fluoroscopy. The main body of the RF Anchor Wire provides a stiff rail for advancing ancillary devices into the left atrium following creation of an atrial septal defect. The proximal end is curved and is bare metal to connect with the included BMC Connector Cable for connection to the compatible BMC RF Puncture Generator.

Comparison to Predicate Devices

Table 2 provides a comparison of the main characteristics of the ProTrack RF Anchor Wire to those of the predicate devices.

Table 2: Comparison of ProTrack RF Anchor Wire Characteristics to Predicate Devices

Characteristic	Comment
Intended Use	Identical
Indications for Use	Similar
Fundamental scientific technology	Identical
Operating principles	Identical
Mechanism of action	Identical
Materials	Similar
Dimensions	Similar
Accessory devices	Identical
Packaging configuration	Similar
Sterilization method and Sterility Assurance Level	Identical

Performance Testing

Performance testing was completed for the ProTrack RF Anchor Wire to support its safety and effectiveness for its intended use and its substantial equivalence to the predicate devices. The following bench top verification and validation was completed:

1. Biocompatibility Verification: The biological safety of the device was verified as per the requirements of ISO 10993-1 and FDA's modified ISO guidelines in accordance with *FDA's blue book memorandum #G95-1 on biocompatibility*.
2. Mechanical Verification: Mechanical testing was performed to verify compliance of the device with ISO 11070 and Baylis self-enforced requirements.
3. Electrical Verification: Electrical testing was performed to verify compliance of the device with IEC 60601-2-2 and Baylis self-enforced requirements.
4. Arc Integrity Verification: Thermal testing was performed to ensure compatibility of the device with the BMC RF Puncture Generator.
5. Benchtop Validation: Validation testing was performed to demonstrate compatibility with accessory devices, radiopacity, and cutting performance as compared to the predicate devices.

The ProTrack RF Anchor Wire met all requirements as specified by the test protocols.

Conclusions

The proposed and predicate devices share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. Differences in design and technological characteristics between the proposed and predicate devices do not raise any new concerns of safety and effectiveness. The results of verification and validation provide reasonable assurance of the safety and effectiveness of the ProTrack RF Anchor Wire for its intended use and its substantial equivalence determination to the predicate devices.