Marblehead Medical, LLC
Kristin Mortenson
Director of Quality and Regulatory
753 Fox Chase Road SW
Rochester, Minnesota 55902-8749

January 28, 2021

Re: K203840
Trade/Device Name: BOSS 8F Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: December 29, 2020
Received: December 31, 2020

Dear Kristin Mortenson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203840

Device Name
BOSS 8F Balloon Guide Catheter

Indications for Use *(Describe)*
The BOSS™ 8F Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these procedures. The balloon guide catheter is also indicated for use as a conduit for retrieval devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BOSS™ 8F Balloon Guide Catheter
510(k) Summary

SUBMITTER [807.92(a)(1)]

Submitter's Name:	Marblehead Medical, LLC
Address:	753 Fox Chase Rd SW, Rochester MN 55902-8749
Contact Person:	Kristin Mortenson
Telephone:	(612) 202-1142
email	Mortenson.Kristin@MarbleheadMedical.com
Date Prepared:	Jan 25, 2021

DEVICE [807.92(a)(2)]

Device Trade Name:	BOSS™ 8F Balloon Guide Catheter
Common Name:	Balloon Guide Catheter
Classification Name:	Percutaneous Catheter
Product Code:	QJP, DQY
Regulatory Class:	Class II
Regulation Number:	21 CFR 870.1250

PREDICATE [807.92(a)(3)]

Primary Predicate Device:	BOSS Balloon Guide Catheter, K200910

DEVICE DESCRIPTION [807.92(a)(4)]

The BOSS 8F Balloon Guide Catheter system is a sterile, single-use intravascular catheter. The BOSS 8F Balloon Guide Catheter is an 85 and 95 cm long, variable stiffness catheter utilizing a bifurcated dual port luer hub on the proximal end and a radiopaque marker band at the tip distal to the balloon. The catheter shaft has an annular inflation lumen and a coaxial central lumen with stainless steel coil and is braid reinforced. The hub central port leads to the central lumen to facilitate introduction of interventional devices through the central lumen. The inflation port is positioned at an angle to the central port, connecting to the annular inflation lumen, and is used to facilitate inflating and deflating the balloon with a syringe. The BOSS 8F Balloon Guide Catheter uses a distal hydrophilic coating to provide lubricity and reduce friction between the catheter shaft and the vessel wall. The BOSS 8F Balloon Guide Catheter is packaged with the 6F dilator to facilitate the option of direct access into the blood vessel without the use of an introducer sheath.

INDICATION FOR USE [807.92(a)(5)]

The BOSS 8F Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these procedures. The balloon guide catheter is also indicated for use as a conduit for retrieval devices.

PREDICATE DEVICE COMPARISON [807.92(a)(6)]

The following table provides a comparison of the key characteristics of the BOSS 8F Balloon Guide Catheter System to the predicate devices.

Feature	Predicate Device	Subject Device
	BOSS Balloon Guide Catheter System	**BOSS 8F Balloon Guide Catheter System**
FDA Classification	Same	Same
Product Code(s)	QJP, DQY	Same
Regulation Number	Same	Same
Regulation Name	Percutaneous Catheter	Same
Indications for Use	The BOSS™ Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these procedures. The balloon guide catheter is also indicated for use as a conduit for retrieval devices.	Same
Anatomical Locations	Peripheral and neurovasculature	Same
Principle of Operation	The Balloon Guide Catheter is used to facilitate the selective placement of interventional devices. After needle access and insertion of up to a 0.038" guidewire into the femoral artery, the device is inserted into the artery through an introducer sheath over the guidewire. The lumen of device is used for insertion and guidance of an intravascular catheter and / or retrieval devices into a selected blood vessel for treatment. Operation includes the direct access use option without an introducer sheath	Same
Material	Commonly used medical grade plastics and stainless steel	Same
Reinforced Catheter Shaft Reinforcement	Stainless Steel coil and braid reinforced	Same
Marker Band / Location	Radiopaque marker 0.08-in (2 mm) wide, 0.02-in (0.5mm) from the distal tip edge distal to the balloon.	Marker band 1.3 mm, 2 mm from distal tip edge distal to the balloon. Similar, difference does not raise new questions regarding safety and efficacy, all devices utilize radiopaque marker bands
Compliant Balloon	Yes, polyurethane	Same
Labeled Shaft Outer Diameter	0.123-in (max) (3.1mm) 9.4Fr	0.111" (2.8 mm) 8F Similar, differences do not raise

Feature	Predicate Device	Subject Device
	BOSS Balloon Guide Catheter System	**BOSS 8F Balloon Guide Catheter System**
		new questions of safety and efficacy.
Labeled Shaft Inner Dimension	0.088-in (2.24 mm) 6.7F	0.0870" (2.2 mm) Similar, differences do not raise new questions of safety and efficacy
Effective length	90 cm	85 and 95 cm Similar, differences do not raise new questions of safety and efficacy.
Tip Shape	Straight	Same
Maximum Balloon Volume	0.6 mL	Same
Radiopaque	Distal Tip has radiopaque marker bands, stainless steel reinforcement in the catheter shaft renders the shaft visible on fluoroscopy	Same
Coating	Coating is on the distal portion proximal to the balloon	Same
Internal Construction	Coaxial Lumen	Same
Supplied items / accessories	Dilator is provided	Same
How Supplied	Sterile, single use	Same
Sterilization Method	EtO	Same
Sterility Assurance Level	10^{-6}	Same

The differences between the subject device and predicates described in the comparison table above are not critical to the intended therapeutic or surgical use of the device, do not raise questions of safety and effectiveness, and as shown through testing and analysis, do not affect the safety and effectiveness of the device when used as labeled.

NONCLINICAL PERFORMANCE TESTING SUMMARY [807.92(b)]

Determination of substantial equivalence is based on an assessment of non-clinical performance bench test data. The BOSS 8F Balloon Guide Catheter System has successfully completed the following relevant performance testing to demonstrate substantial equivalence. Testing was performed to evaluate physical integrity, functionality, and performance of the BOSS 8F Guide Catheter. A summary of the tests performed is provided in the table below:

Performance Bench Testing Summary			
Study Name	**Description**	**Reference Standard**	**Results**
Visual Inspection and Dimensional Verification	To demonstrate that the product meets the dimensional specifications	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Surface Inspection	To demonstrate the product satisfies the visual surface requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Torque Testing	To demonstrate that the product is capable of 360 degrees of rotation about the central lumen axis without failure.	FDA guidance PTCA Catheters:2010 §VIII.A.10	Pass All samples met the pre-determined acceptance criteria
Tensile	To demonstrate the product satisfies the tensile strength requirements for bonds and tip pull test	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements, FDA guidance PTCA Catheters:2010 §VIII.A.7, 8	Pass All samples met the pre-determined acceptance criteria
Kink Resistance	To demonstrate that the product has acceptable kink resistance	FDA Guidance PTCA:2010 §VIII.A.9 Kink Test	Pass All samples met the pre-determined acceptance criteria
Catheter Lubricity	Pad friction test to compare coated to uncoated samples	Characterization only	Results show a 97% reduction in friction compared to uncoated samples
Particulates, Coating Integrity	This study was conducted to determine the quantity and size of particles generated during simulated use	AAMI TIR42:10 Evaluation of particulates associated with vascular medical devices, USP <788> Particulate Matter in Injections	Pass All samples met the pre-determined acceptance criteria
Radiopacity	To determine the radiopaque characteristics of the device.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria

Performance Bench Testing Summary			
Study Name	**Description**	**Reference Standard**	**Results**
Push/Track, Simulated Use, Device Compatibility	To demonstrate that the device is deliverable through tortuous path model without kinking or buckling, is able inflate, deflate balloon at target, is compatible with treatment devices and removed without damage.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
System Leak - Liquid Leak	To demonstrate that the product meets the liquid leakage under pressure requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
System Leak - Aspiration	To demonstrate that the product meets the hub aspiration air leakage requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Tip Stiffness	To demonstrate that the stiffness of the distal end of the product is similar to other marketed devices.	N/A	Pass All samples met the pre-determined acceptance criteria
Corrosion Resistance	To demonstrate the product satisfies the corrosion resistance requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Catheter Burst Pressure Under Static Conditions	To demonstrate the catheter does not leak or rupture up to rated internal pressure.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Balloon Inflation / Deflation	To demonstrate balloon meets the inflation and deflation time specifications	ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria
Balloon Fatigue	To demonstrate that there is no degradation of the balloon after 10 inflation cycles.	ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria

Performance Bench Testing Summary			
Study Name	**Description**	**Reference Standard**	**Results**
Balloon Diameter / Volume	To demonstrate that the product meets the inflation volume vs balloon diameter specifications	ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria
Balloon Rated Burst Volume	To demonstrate that the balloon is capable of withstanding an injection volume to the rated burst volume	ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria
Small Bore Connector Compliance with Standard	To demonstrate that the product meets the requirements for small bore connectors	ISO 80369-7: 2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7, Connectors for intravascular or hypodermic applications.	Pass All samples met the pre-determined acceptance criteria
Usability Study / Simulated Use	Evaluation of device performance to meet the user needs under simulated use conditions with accessories and treatment devices	FDA Guidance Human Factors and Usability Engineering 2016, IEC 62366:2015	Pass All samples met the pre-determined acceptance criteria
Conditioning, Distribution, and Shelf-life Aging	To demonstrate the device met all specifications at both baseline (T=0) and following accelerated aging to a 6-month shelf life equivalent (T=6)	Evaluation of device following accelerated aging to a 6-month shelf life equivalent	Pass All samples met the pre-determined acceptance criteria
Package Testing			
Conditioning, Distribution, and Shelf-Life Aging	Evaluation of packaging strength and integrity at both baseline (T=0) and following accelerated aging to a 6-month shelf life equivalent (T=6)	ISTA procedure 3A (2018), ASTM D4169-16, ASTM F1980-16, ASTM F88-15, ASTM F2096-11, ASTM 1929-15	Pass All samples met the pre-determined acceptance criteria
Visual Inspection Packaging and Labeling	To demonstrate that the product meets the packaging and labeling visual and adherence requirements	N/A	Pass All samples met the pre-determined acceptance criteria

The results of these tests provide reasonable assurance that the BOSS 8F Balloon Guide Catheter has been designed and tested to assure conformance to the requirements for its intended use and

indications for use. No new safety or performance issues were raised during the testing; therefore, this device is considered to be substantially equivalent to the predicate devices.

Biocompatibility Testing Summary

The device is categorized as Externally Communicating Device, Circulating Blood, Limited Contact (≤ 24 hours), per ISO 10993-1, the following testing was conducted:

Test Name	Test Method	Results
Cytotoxicity	Tested in accordance with ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for *in vitro* toxicity, Neutral Red Uptake Method	Pass Noncytotoxic according to the predetermined acceptance criteria
Intracutaneous Irritation	Tested in accordance with ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Pass Test requirements for intracutaneous reactivity were met according to the predetermined acceptance criteria
Sensitization	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10 Tests for Irritation and Skin Sensitization, Kligman Maximization Test	Pass Did not elicit a sensitization response according to the predetermined acceptance criteria
Systemic Toxicity	Tested in accordance with ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	Pass Test requirements for systemic toxicity were met according to the predetermined acceptance criteria
Material Mediated Pyrogenicity	Tested in accordance with ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity and USP 40 <151> Pyrogen Test	Pass Nonpyrogenic, met the predetermined acceptance criteria
Hemolysis	Tested in accordance with ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, Tests for Hemolytic Properties, Direct and Indirect Methods	Pass Non-hemolytic, met the predetermined acceptance criteria
Complement Activation	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4:2017: Selection of Tests for Interactions with Blood, SC5b-9 Complement Activation	Pass Demonstrates similar complement activation characteristics as the control device, met the predetermined acceptance criteria

Test Name	Test Method	Results
In vivo Thromboresistance	Tested in accordance with ISO 10993-4:2017, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood	Pass Demonstrates similar thromboresistance characteristics as the control device, met the predetermined acceptance criteria

Sterilization and Shelf Life

The BOSS 8F Balloon Guide Catheter sterilization process using 100% Ethylene Oxide (EO) has been validated in accordance with ISO 11135-1:2014 to achieve a SAL of 10^{-6}. EO and ECH residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels (BET) were below the level of 2.15 EU/device in accordance with ANSI AAMI ST72:2011/(R)2016. Both baseline and accelerated shelf-life testing were conducted (T = 0 and T = 6-month AA (accelerated aging)) demonstrating the device will perform as intended to support the proposed 6-month shelf-life.

Animal Testing

No animal studies were required to demonstrate substantial equivalence.

Clinical Testing

No clinical studies were required to demonstrate substantial equivalence.

Conclusion

Marblehead Medical LLC concludes through a review of the benchtop assessments, the comparison of the device classification, intended use, operating principle, technological characteristics, sterility, and biocompatibility that the BOSS 8F Balloon Guide Catheter System is substantially equivalent to the predicate device.