

5. 510(k) Summary

MAY 11 2012

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K120119

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SUMMARY

K Reference # K120119
Submitter's name: Sunny Medical Device (Shenzhen) Co., Ltd.
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Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411
Fax: 949-552-2821
Date the summary was revised: May 8, 2012
Name of the device: Sunmed Guide Wires
Trade or proprietary name Sunmed Guide Wires
Common or usual name Guide wires

Product Code	Classification Regulation	Classification Name
DQX	870.1330	Catheter guide wire

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

	510(k)	Trade or Proprietary or Model Name	Manufacturer
1	K993000	Bard Hydrophilic Coated Guide Wires	C.R. Bard Inc.
2	K082094	PTFE (Teflon) Coated Guide Wires	C.R. Bard Inc.

Description of the device:

Sunmed Guidewires are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion.

The Sunmed Guide Wires are available in three versions with a variety of tips:

- Stainless steel guide wire
- Hydrophilic coated guide wire
- PTFE (Teflon®) coated guide wires

The Seldinger technique is used with these guidewires.

The stainless steel guide wires are standard wires with various tip configurations. The guide wire construction consists of a safety wire, a core wire, and a wound spring for flexibility. The features that distinguish individual wires consist of the core type (fixed or moveable), a straight or "J" tip configuration, diameters and lengths.

The Hydrophilic coated guide wires are constructed from the stainless steel core wire, with varying core lengths and diameters for each design.

The PTFE (Teflon®) coated guide wires are also manufactured from stainless steel wire, with PTFE (Teflon®) coating, or Benzalkonium Heparin (BH) coating applied over the PTFE (Teflon®) coating.

These guide wires are radiodetectable and fluoroscopy may be used to confirm position.

These medical devices are single use and supplied sterile by EO.

List of devices and predicate K reference numbers:

DIAMETER	LENGTH	TIP	COATING	SUNNY CATALOG #	BARD K #
0.035	45	3 mm J	PTFE	SM-GW-3J35045P-TP	K082094
0.035	50	1.5 mm J	PTFE	SM-GW-1J35050P-TP	K082094
0.025	80	Straight	PTFE	SM-GW-3S25080P-TP	K082094
0.032	80	Straight	PTFE	SM-GW-3S32080P-TP	K082094
0.035	80	Straight	PTFE	SM-GW-3S35080P-TP	K082094
0.035	80	3 mm J	PTFE	SM-GW-3J35080P-TP	K082094
0.038	80	Straight	PTFE	SM-GW-3S38080P-TP	K082094
0.025	100	Straight	PTFE	SM-GW-3S25100P-TP	K082094
0.025	100	3 mm J	PTFE	SM-GW-3J25100P-TP	K082094
0.035	100	Straight	PTFE	SM-GW-3S35100P-TP	K082094
0.035	100	3 mm J	PTFE	SM-GW-3J35100P-TP	K082094
0.038	100	Straight	PTFE	SM-GW-3S38100P-TP	K082094
0.038	100	3 mm J	PTFE	SM-GW-3J38100P-TP	K082094
0.025	120	Straight	PTFE	SM-GW-3S25120P-TP	K082094
0.025	120	3mm J	PTFE	SM-GW-3J25120P-TP	K082094
0.032	120	Straight	PTFE	SM-GW-3S32120P-TP	K082094
0.032	120	3 mm J	PTFE	SM-GW-3J32120P-TP	K082094
0.035	120	Straight	PTFE	SM-GW-3S35120P-TP	K082094
0.035	120	1.5 mm J	PTFE	SM-GW-1J35120P-TP	K082094
0.035	120	3 mm J	PTFE	SM-GW-3J35120P-TP	K082094
0.035	120	6 mm J	PTFE	SM-GW-6J35120P-TP	K082094
0.038	120	Straight	PTFE	SM-GW-3S38120P-TP	K082094
0.038	120	3 mm J	PTFE	SM-GW-3J38120P-TP	K082094
0.045	120	Straight	PTFE	SM-GW-3S45120P-TP	K082094
0.018	145	Straight	PTFE	SM-GW-3S18145P-TP	K082094
0.024	145	3 mm J	PTFE	SM-GW-3J24145P-TP	K082094
0.025	145	Straight	PTFE	SM-GW-3S25145P-TP	K082094
0.025	145	1.5 mm J	PTFE	SM-GW-1J25145P-TP	K082094
0.028	145	Straight	PTFE	SM-GW-3S28145P-TP	K082094
0.028	145	1.5 mm J	PTFE	SM-GW-1J28145P-TP	K082094
0.028	145	3 mm J	PTFE	SM-GW-3J28145P-TP	K082094
0.032	145	Straight	PTFE	SM-GW-3S32145P-TP	K082094
0.032	145	1.5 mm J	PTFE	SM-GW-1J32145P-TP	K082094
0.032	145	3 mm J	PTFE	SM-GW-3J32145P-TP	K082094
0.035	145	Straight	PTFE	SM-GW-3S35145P-TP	K082094
0.035	145	1.5 mm J	PTFE	SM-GW-1J35145P-TP	K082094
0.035	145	3 mm J	Heparin	SM-GW-3J35145E-TP	K082094
0.035	145	3 mm J	PTFE	SM-GW-3J35145P-TP	K082094
0.035	145	6 mm J	PTFE	SM-GW-6J35145P-TP	K082094
0.038	145	Straight	PTFE	SM-GW-3S38145P-TP	K082094
0.038	145	3 mm J	Heparin	SM-GW-3J38145E-TP	K082094

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DIAMETER	LENGTH	TIP	COATING	SUNNY CATALOG #	BARD K #
0.038	145	3 mm J	PTFE	SM-GW-3J38145P-TP	K082094
0.038	145	6 mm J	PTFE	SM-GW-6J38145P-TP	K082094
0.045	145	Straight	PTFE	SM-GW-3S45145P-TP	K082094
0.065	145	Straight	PTFE	SM-GW-3S65145P-TP	K082094
0.038	150	Straight	PTFE	SM-GW-3S38150P-TP	K082094
0.038	150	3 mm J	PTFE	SM-GW-3J38150P-TP	K082094
0.035	175	3 mm J	PTFE	SM-GW-3J35175P-TP	K082094
0.025	200	1.5 mm J	PTFE	SM-GW-1J25200P-TP	K082094
0.032	200	Straight	PTFE	SM-GW-3S32200P-TP	K082094
0.032	200	1.5 mm J	PTFE	SM-GW-1J32200P-TP	K082094
0.035	200	Straight	PTFE	SM-GW-3S35200P-TP	K082094
0.035	200	1.5 mm J	PTFE	SM-GW-1J35200P-TP	K082094
0.035	200	3 mm J	PTFE	SM-GW-3J35200P-TP	K082094
0.038	200	Straight	PTFE	SM-GW-3S38200P-TP	K082094
0.025	220	Straight	PTFE	SM-GW-3S25220P-TP	K082094
0.035	220	Straight	PTFE	SM-GW-3S35220P-TP	K082094
0.035	220	3 mm J	PTFE	SM-GW-3J35220P-TP	K082094
0.038	220	Straight	PTFE	SM-GW-3S38220P-TP	K082094
0.035	260	Straight	PTFE	SM-GW-3S35260P-TP	K082094
0.035	260	3 mm J	PTFE	SM-GW-3J35260P-TP	K082094
0.038	260	Straight	PTFE	SM-GW-3S38260P-TP	K082094
0.035	300	Straight	PTFE	SM-GW-3S35300P-TP	K082094
0.035	400	Straight	PTFE	SM-GW-3S35400P-TP	K082094
0.025	145	Straight	Hydrophilic	SM-GW-3S25145H-TP	K993000
0.035	145	Straight	Hydrophilic	SM-GW-3S35145H-TP	K993000
0.038	145	Straight	Hydrophilic	SM-GW-3S38145H-TP	K993000
0.032	40	Straight	302 Stainless Steel	SM-GW-3S32040N-TP	Pre-amendment
0.025	45	3 mm J	302 Stainless Steel	SM-GW-3J25045N-TP	Pre-amendment
0.035	45	Straight	302 Stainless Steel	SM-GW-3S35045N-TP	Pre-amendment
0.035	45	3 mm J	302 Stainless Steel	SM-GW-3J35045N-TP	Pre-amendment
0.038	45	Straight	302 Stainless Steel	SM-GW-3S38045N-TP	Pre-amendment
0.038	50	3 mm J	302 Stainless Steel	SM-GW-3J38050N-TP	Pre-amendment
0.032	80	Straight	302 Stainless Steel	SM-GW-3S32080N-TP	Pre-amendment
0.035	80	3 mm J	302 Stainless Steel	SM-GW-3J35080N-TP	Pre-amendment
0.035	100	Straight	302 Stainless Steel	SM-GW-3S35100N-TP	Pre-amendment

DIAMETER	LENGTH	TIP	COATING	SUNNY CATALOG #	BARD K #
0.035	100	3 mm J	302 Stainless Steel	SM-GW-3J35100N-TP	Pre-amendment
0.038	100	Straight	302 Stainless Steel	SM-GW-3S38100N-TP	Pre-amendment
0.038	100	3 mm J	302 Stainless Steel	SM-GW-3J38100N-TP	Pre-amendment
0.045	100	Straight	302 Stainless Steel	SM-GW-3S45100N-TP	Pre-amendment
0.035	120	Straight	302 Stainless Steel	SM-GW-3S35120N-TP	Pre-amendment
0.035	120	3 mm J	302 Stainless Steel	SM-GW-3J35120N-TP	Pre-amendment
0.038	120	Straight	302 Stainless Steel	SM-GW-3S38120N-TP	Pre-amendment
0.038	120	3 mm J	302 Stainless Steel	SM-GW-3J38120N-TP	Pre-amendment
0.045	120	Straight	302 Stainless Steel	SM-GW-3S45120N-TP	Pre-amendment
0.035	145	Straight	302 Stainless Steel	SM-GW-3S35145N-TP	Pre-amendment
0.035	145	3 mm J	302 Stainless Steel	SM-GW-3J35145N-TP	Pre-amendment
0.038	145	Straight	302 Stainless Steel	SM-GW-3S38145N-TP	Pre-amendment
0.038	145	3 mm J	302 Stainless Steel	SM-GW-3J38145N-TP	Pre-amendment
0.035	250	Straight	302 Stainless Steel	SM-GW-3S35250N-TP	Pre-amendment
0.038	260	Straight	302 Stainless Steel	SM-GW-3S38260N-TP	Pre-amendment
0.038	300	Straight	302 Stainless Steel	SM-GW-3S38300N-TP	Pre-amendment
0.035	400	Straight	302 Stainless Steel	SM-GW-3S35400N-TP	Pre-amendment

Package:

Material No.1: DuPont Tyvek package for medical use. Material No.2:
Multiple-layer compound film made from of PE and PA.

Indications:

Sunmed Guidewires are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion.

Performance Testing:

The following tests were performed on the Sunmed Guide Wires:

Degradation Test on Disposable Guide Wire

Physical Performance

Appearance

Radiodetectability

Eroding resistance

Breakage resistance

Deformation resistance

Connection strength

Package Performance

Sterility

ETO Residue

ECH Residue

Technological Characteristics:

Summary of the technological characteristics of our device compared to the predicate device:

The predicates were compared in the following areas and found to have identical technological characteristics and to be equivalent because they are the identical products.

Indications for Use

Target Population

Design

Technique

Sterility

Biocompatibility

Anatomical Sites



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

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Sunny Medical Device (Shenzhen) Co., Ltd.
c/o Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K120119
Sunmed Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 20, 2012
Received: May 10, 2012

Dear Mr. Holland:

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.

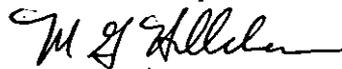
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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,



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

Enclosure

