

APR 16 2010

a.

Device Information:

| Category | Comments |
|---------------------------------------|---|
| Sponsor: | Guided Delivery Systems, Inc 2355 Calle de Luna Santa Clara, CA 95054 |
| Correspondent Contact Information: | Bonnie McInerney, Manager, Regulatory & Quality Guided Delivery Systems, Inc 2355 Calle de Luna Santa Clara, CA 95054 Tel: 408 727 1105 x227 Fax: 408 727 6615 Email: bmcinerney@gdsmed.com |
| Device Common Name: | Cardiac Introducer Sheath |
| Device Classification Number: | 21 CFR §870.1340 |
| Device Classification & Product Code: | Class II (two); DYB |
| Device Proprietary Name: | GDS-DC12 |

Predicate Device Information:

| | |
|---|---------------------------------------|
| Predicate Device: | GDS-DC6 Catheter |
| Predicate Device Manufacturer: | Guided Delivery Systems |
| Predicate Device Premarket Notification # | K091367 |
| Predicate Device Common Name: | Cardiac Introducer |
| Predicate Device Classification & Name: | 21 CFR §870.1340; Catheter introducer |
| Predicate Device Classification & Product Code: | Class II (two); DYB |

Predicate Device Information:

| | |
|---|---------------------------------------|
| Predicate Device: | Enpath Deflectable Catheter |
| Predicate Device Manufacturer: | Bard, Enpath Medical |
| Predicate Device Premarket Notification # | K043489 |
| Predicate Device Common Name: | Cardiac Introducer |
| Predicate Device Classification & Name: | 21 CFR §870.1340; Catheter introducer |
| Predicate Device Classification & Product Code: | Class II (two); DYB |

b. Date Summary Prepared

April 5, 2010

c. Description of Device

GDS-DC12 is a polymeric, single use, sterile, non-pyrogenic, disposable intracardiac catheter of various sizes and curvatures with a deflectable tip and hemostasis valve.

d. Intended Use

GDS-DC12 is intended to facilitate the intracardiac placement of interventional devices such as guidewires.

e. Comparison to Predicate Device

The GDS-DC12 catheter is substantially equivalent in intended use, fundamental technology, and design to the GDS-DC6 and the Enpath Deflectable Catheter. Each of the catheters is a polymeric, single lumen shaft that is advanced through the vasculature to reach a chamber within heart. Other interventional devices can be introduced through each of the catheters.

The GDS-DC12 catheter is substantially equivalent in physician use to the GDS-DC6 and the Enpath Deflectable Catheter. All the catheters are intended for use under fluoroscopic guidance by physicians trained in interventional cardiology procedures. The GDS-DC12 and the GDS-DC6 contain barium sulfate filled tubing for radiopacity.

f. Summary of Supporting Data

The clearance of this device was based in part on the evaluation of the following performance characteristics:

- Dimensional measurements (OD, ID, Lengths)
- Torsional Response
- Pull Wire Movement
- Corrosion Resistance
- Shaft to Hub Tensile
- Shaft Tensile
- Pull Wire Tension
- Tip Tensile
- Torque Test
- Shaft Leak Under Pressure
- Shaft Leak Under Vacuum
- Catheter Flexibility/ Kink Resistance
- Catheter Turns To Failure
- Radiopacity (leveraged from GDS-DC6 K091367)
- Biocompatibility

Predicate information is provided in appendix A.

Bench testing data (appendix B) has demonstrated that the device is in compliance with design input requirements, the expectations of the medical community and the product labeling.

Sterilization, packaging and shelf life testing (appendix C) demonstrates that the device is sterile, the packaging is robust and that it maintains a sterile barrier for the stated expiration time.

Biocompatibility data (appendix D) demonstrates that the device is biocompatible and in compliance with ISO 10993.

g. Conclusion

The GDS-DC12 is substantially equivalent in intended use, technology, design and materials to the predicate devices. The testing described above demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy. Therefore, Guided Delivery Systems, Inc. concludes that the devices are substantially equivalent.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Guided Delivery Systems, Inc
c/o Ms. Bonnie McInerney
Manager, Regulatory & Quality
2355 Calle de Luna
Santa Clara, CA 95054

APR 16 2010

Re: K100135
Trade/Device Name: GDS-DC 12 Catheter
Common Name: Catheter, Introducer
Regulation Number: 21 CFR §870.1340
Regulatory Class: II
Product Code: DQY
Dated: January 14, 2010
Received: January 19, 2010

Dear Ms. McInerney:

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.

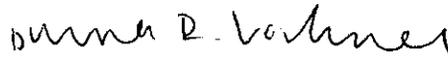
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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" (21CFR 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,



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

Enclosure

Indications for Use Statement

510(k) Number K0100135
Device Name: GDS-DC12

Indications for Use:

GDS-DC12 is intended to facilitate the intracardiac placement of interventional devices such as guidewires.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Anna R. Rodman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100135