K101518

OCT 13 2010

Mirador Biomedical

SECTION 5: 510(k) SUMMARY

In accordance with the requirements of 21 CFR 807.92(c) Mirador Biomedical, Inc. (hereafter "Mirador") has prepared this 510(k) Summary to provide information supporting the substantial equivalence of the Mirador Compass™.

General Information:

Date of Summary Preparation:	June 1, 2010
Name and Address of Manufacturer:	Mirador Biomedical, Inc. 2815 Eastlake Ave Suite 300 Seattle, Washington 98102
Contact Person:	Justin Hulvershorn, MD, PhD Chief Science Officer Phone: (206) 295-3372
Trade Names:	Compass™ Vascular Access Compass™ Lumbar Puncture
Common Name:	Disposable Pressure Transducer
Device Classification:	Extravascular Blood Pressure Transducer Single-Function, Preprogrammed Diagnostic Computer
Classification Panel:	Cardiovascular
CFR Reference:	870.2850 870.1435
Product Code:	DRS DXG
Device Class:	Class II

Device Description: The Compass is a disposable, point-of-use pressure measurement and monitoring device that incorporates a pressure transducer and an integrated pre-programmed diagnostic computer with liquid crystal display (LCD). The Compass is provided as two different models, each corresponding to a specific indication for use:

(1) The Compass Vascular Access (VA) is for invasive blood pressure measurement and monitoring during the insertion of vascular access devices.

(2) The Compass Lumbar Puncture (LP) is for intracranial pressure measurement and monitoring via lumbar puncture or intraventricular catheter.

Both models are designed to attach distally to an inserted needle or catheter, measure the pressure via an embedded pressure sensor, internally convert changes in pressure into electrical currents, and then display the resulting pressure via the integrated LCD.

The Compass VA and Compass LP devices are identical except for two differences: 1) the measurement units in which the pressure is displayed on the LCD (mm Hg for blood pressure measurements with the Compass VA and cm H_2O for intracranial pressure measurements with the Compass LP), and 2) the Compass VA blood pressure monitoring device has a proximal port through which commercially available guidewires can be inserted during pressure measurement.

Indications for Use: Consistent with the above device description, the Compass VA and Compass LP devices respectively possess the following indications for use:

The Compass™ Vascular Access is a disposable pressure transducer with integrated digital display intended for direct measurement and monitoring of invasive blood pressure.

The Compass™ Lumbar Puncture is a disposable pressure transducer with integrated digital display intended for direct measurement and monitoring of intracranial pressure.

Substantially Equivalent Predicate Devices: The Compass VA and Compass LP are substantially equivalent to the following legally marketed devices with respect to classification, design principles and/or indications for use:

- Shenzhen Disposable Pressure Transducer – K091408
- Vigileo APCO/Oximetry Monitor and DDPT – K043065
- Stryker Intra-Compartmental Pressure Monitor System – K844214

Device Testing: Performance testing of the Compass VA and Compass LP devices included *in vitro* (bench), biocompatibility, packaging, sterilization, software validation, electrical/EMC, and *in vivo* animal.

All testing was completed per Mirador Biomedical's in-house test methods, protocols, and requirements or in accordance with applicable recognized standards by accredited outside laboratories.

Biocompatibility testing was completed per ISO 10993-1 and included cytotoxicity, hemolysis, acute systemic toxicity, intracutaneous reactivity, sensitization and pyrogenicity.

With respect to device performance, this included, but was not limited to, applicable functional testing per ANSI/AAMI BP22:1994(R)2006, ISO 594-1 and ISO 594-2. A listing of all *in vitro* performance testing is as follows:

- Luer Fittings
- Mechanical Strength and Durability
- Power Switch
- Dimensional and Weight Verification
- Battery Life
- Pressure Overrange Capability
- Pressure Accuracy
- Drift, Temperature Error Band, and Temperature Error Band of Sensitivity
- Light Sensitivity
- Frequency Response
- Guidewire Testing
- Spillage
- Safety
- Simulated Use Testing – Vascular Access
- Simulated Use Testing – Lumbar Puncture

The results from this *in vitro* testing demonstrate that the technological and performance characteristics of the Compass VA and Compass LP devices meet defined design requirements and that they can perform in a manner equivalent to devices currently on the market used for measuring and monitoring invasive blood pressure and intracranial pressure.

The *in vivo* animal study was completed using a swine model and assessed performance of the Compass VA to measure arterial and venous blood pressures and the Compass LP to measure intracranial pressures via lumbar puncture. The predicate Shenzhen DPT pressure sensor was used for relative comparison. The results of this study demonstrate that the Compass VA and Compass LP devices can each be used as intended to accurately measure and monitor their labeled physiologic pressures (i.e., invasive blood pressure or intracranial pressure) in a manner equivalent to the predicate device.

Conclusion (Statement of Equivalence): The data and information presented within this submission support a determination of substantial equivalence, and therefore market clearance of Compass VA and Compass LP devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 1 8 2010

Mirador Biomedical, Inc.
c/o Dr. Justin Hulvershorn
Chief Science Officer
2815 Eastlake Avenue Suite 300
Seattle, WA 98102

Re: K101518
Trade/Device Name: Compass Vascular Access and Compass Lumbar Puncture
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DRS, DXG
Dated: August 24, 2010
Received: August 25, 2010

Dear Dr. Hulvershorn:

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 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,

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

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K101518

Device Names: Compass™ Vascular Access
Compass™ Lumbar Puncture

Indications for Use:

The Compass™ Vascular Access is a disposable pressure transducer with integrated digital display intended for direct measurement and monitoring of invasive blood pressure.

The Compass™ Lumbar Puncture is a disposable pressure transducer with integrated digital display intended for direct measurement and monitoring of intracranial pressure.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101518