APR 1 8 2014

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™ CT and CT Port.

General Information:

Date of Summary Preparation:	November 20, 2013
Name and Address of Manufacturer:	Mirador Biomedical, Inc. 2815 Eastlake Ave E. Suite 220 Seattle, Washington 98102
Contact Person:	Justin Hulvershorn, MD, PhD Chief Science Officer Phone: (206) 295-3372
Trade Names:	Compass™ CT Port Compass™ CT
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 CT and Compass CT Port are disposable, point-of-use pressure measurement and monitoring devices that incorporate a pressure transducer and an integrated pre-programmed diagnostic computer with liquid crystal display (LCD). The devices have a distal male luer fitting to connect to a needle or catheter, and a proximal female luer fitting that can be connected to accessory devices (e.g. syringes, caps, or infusion tubing). The devices 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 CT Port has an additional, sealed proximal port through which commercially available guidewires can be inserted during pressure measurement.

Indications for Use: Consistent with the above device description, the devices possess the following indications for use:

The Compass™ CT disposable pressure transducer with integrated digital display is intended for direct measurement and monitoring of physiological pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

The Compass™ CT Port disposable pressure transducer with integrated digital display is intended for direct measurement and monitoring of physiological pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

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

- Compass Compartment Pressure – K112203
- Compass Vascular Access Port – K101518

Device Testing: The subject Compass CT and CT Port are new Compass models in an existing Mirador product line of disposable pressure sensors with integrated digital displays. The Compass CT device incorporates the exact physical elements (e.g. plastic housing, electronics) contained in the predicate Compass Compartment Pressure device except for a male luer lock on the distal end of the CT device. The Compass CT Port device (which adds a guidewire port) incorporates the exact physical elements contained in the predicate Compass Vascular Access Port except for a male luer lock on the CT Port device.

All applicable functional and biocompatibility testing has been performed on the new male luer lock.

All packaging materials, methods and processes and the sterilization process are *identical* to the predicate Compass Compartment Pressure and Vascular Access Port device. Therefore, all prior packaging, sterilization, and shelf life testing of the predicate Compass devices remain applicable to the subject Compass CT and CT Port devices.

With respect to device performance, given the similarities in design and mechanical operation, tests completed on the predicate Compass Compartment Pressure and Compass Vascular Access Port and included previously in support of Mirador 510(k)s K112203 and K101518 have been used to verify design requirements for the subject Compass CT and CT Port devices. However, the subject Compass CT and CT Port devices incorporate new software that allows for an extended pressure range. Therefore, all verification tests related to the software and pressure accuracy that were completed to support the substantial equivalence of the predicate Compass devices were re-executed for the subject Compass CT and CT Port. Pressure accuracy testing was completed per ANSI/AAMI BP22:1994(R)2006 and ISO 60601-2-34 3rd Ed..

The results from this *in vitro* testing demonstrate that the technological and performance characteristics of the subject Compass CT and CT Port meet defined design requirements and that they can perform in a manner equivalent to devices currently on the market used for measuring physiological pressure.

Conclusion (Statement of Equivalence): The data and information presented within this submission support a determination of substantial equivalence, and therefore market clearance of the subject Compass CT and CT Port.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2014

Mirador Biomedical, Inc.
c/o Justin Hulvershorn, MD, PhD
Chief Science Officer
2815 Eastlake Ave. E Suite 220
Seattle, WA 98102

Re: K133624
Trade/Device Names: Compass™ CT and Compass™ CT Port
Regulatory Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II (Two)
Product Code: DRS, DXG
Dated: March 7, 2014
Received: March 11, 2014

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. 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.

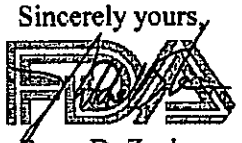
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



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): K133624

Device Names:
Compass™ CT
Compass™ CT Port

Indications for Use:
The Compass™ CT disposable pressure transducer with integrated digital display is intended for direct measurement and monitoring of physiological pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

The Compass™ CT Port disposable pressure transducer with integrated digital display is intended for direct measurement and monitoring of physiological pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

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)

Date: 2014.04.18 18:07:53 -04'00'

Page _1_ of _1__