

SAFETY AND EFFECTIVENESS SUMMARY
Summit Doppler Systems, Inc.
STN Probe

K101816

Name and Address: Summit Doppler Systems, Inc.
4680 Table Mountain Dr. #150
Golden, CO 80403

Phone: (303) 423-7572
Fax: (303) 431-5994

CONTACT: Ken Jarrell – President

Preparation Date: June 25, 2010

Device Name: STN Probe

Common Name: Peripheral Vascular Doppler

Classification: Class II per: FR Number Product Code
Diagnostic ultrasonic transducer 892.1570 ITX

Indications for Use: This product will be used to detect blood flow in veins and arteries.

Description: The LifeDop is a hand-held, battery powered, audio Doppler device used for blood flow detection in veins and arteries. The product includes sterilizable detachable ultrasound transducer probe and user replaceable batteries. The user interface includes an on/off button, volume control, single 2-1/4" speaker and battery. The product is housed in custom injection molded housings. Patient contact materials are ABS and Polycarbonate injection molded plastic.

Substantial Equivalence: Summit Doppler Systems
Golden, CO
LifeDop Doppler Ultrasound System – w/ 8.0 MHz CW PV Probe
K024197, Cleared 1/3/03

Technologies Summary: Doppler ultrasound technology is the same as substantially equivalent device shown above. There is no change in the intended use of the device.

Clinical Testing: None provided

Conclusion: Based on comparisons of device features, materials, intended use and performance, the STN Probe is shown to be substantially equivalent to the commercially available and legally marketed device indicated above.

AUG 19 2010



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

Mr. Ken Jarrell
President
Summit Doppler Systems, Inc.
4680 Table Mountain Dr. #150
GOLDEN CO 90403

AUG 19 2010

Re: K101816
Trade/Device Name: STN Probe
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: July 26, 2010
Received: July 28, 2010

Dear Mr. Jarrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the STN Probe, as described in your premarket notification:

Transducer Model Number

STN Probe - 8 MHz CW PV, Sterilizable

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

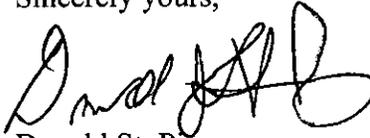
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,



Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

K101816

510(k) Number (if known):

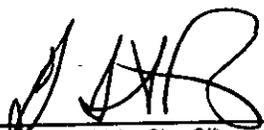
Device Name: STN Probe

Indications For Use: This product will be used to detect blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form

LifeDop Doppler Ultrasound System w/ STN Probe – 8.0 MHz CW PV, Sterilizable

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

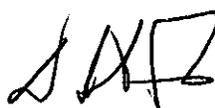
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: LifeDop Doppler Ultrasound System – cleared on K024197, 01/03/2003

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
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Prescription Use (Per 21 CRF 801.109)



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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101816

Diagnostic Ultrasound Indications for Use Form

STN Probe – 8 MHz CW PV, Sterilizable

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

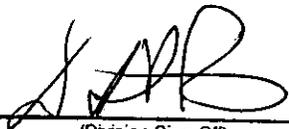
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 8.0 MHz CW PV Probe – cleared on K024197, 01/03/2003

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101816