

SEP 8 1999

510(k) - Medi-Stim Butterfly Flowmeter
510(k) Summary

K992305

4.9. 510(k) Summary

510(k) Summary

as required by 807.92 (c)

for Medi-Stim Butterfly Flowmeter, BF1000 – BF2004

Prepared June 28th, 1999

Submitted by: Medi-Stim A/S
Sandakerveien 110
P.O. Box 35 Grefsen
N-0475 Oslo
Norway
tel. +47 23 05 96 70 (direct), +47 23 05 96 60 (switch board)
fax +47 23 05 96 61

Contact Person: Jon H. Hoem, VP International Sales & Marketing

Device Trade Name: Medi-Stim Butterfly Flowmeter

Common Name: Cardiovascular Blood Flowmeter

Classification: Class II

Predicate Device: Transonic Flowmeter
Transonic Systems. Inc.
34 Dutch Mill Road
Ithaca, NY 14850
K872048

Description of Device:

The Medi-Stim Butterfly Flowmeter estimates blood volume flow by measuring the transit time difference between an ultrasonic signal propagated through a blood vessel in the downstream direction and one propagated in the upstream direction. The measuring unit consists of two ultrasonic transducers on one side of the vessel aimed at a common point on a flat reflector on the other side of the vessel.

Intended Use of Device:

It is intended for accurate transit time blood volume flow measurements during cardiovascular, vascular and transplantation surgery.

Substantial Equivalence to Predicate Device:

The intended use of the Transonic Flowmeter is intraoperatively through a venous or arterial wall of an adult or pediatric patient to measure the approximate instantaneous and average blood volume flow through exposed peripheral and/or cardio-thoracic veins or arteries. It is not intended for fetal use. The same indications for use apply to the Medi-Stim flowmeter.

Both the Medi-Stim Butterfly Flowmeter and the Transonic Flowmeter uses the transit time principle to measure volume flow. The main differences between the systems lie in the implementation and presentation of the measurement results. Medi-Stim has utilized a commercial available platform and developed a transit time technology that interfaces with this platform. The transit time signal processing is performed by hardware that uses algorithms similar to an ultrasound scanner, and the received ultrasound phase shifts are processed digitally. The flowmeter displays the measurement results with a flow curve and it's associated mean flow value. All other measurement results are displayed simultaneously on an active matrix touch screen. The predicate utilizes hardware that needs more calibration points and where the signal processing is mainly analog.

There is also a difference with regard to the design of the transit time probes which in the case of Medi-Stim has a flat front face design providing a more stable and reproducible measurement.

However, there is no safety or effectivity issues associated with these differences. The table below summarizes the differences between the Medi-Stim flowmeter and the predicate device.

Medi-Stim Butterfly Flowmeter vs. the predicate device		
	The Medi-Stim Butterfly Flowmeter	Transonic Flowmeter
1. Intended use	Cardiovascular, vascular and transplantation surgery	Cardiac surgery, vascular reconstructions and transplanted organs
2. Patient group	Adult and pediatric	Adult and pediatric
3. Flow measurements		
Technology	Transit time	Transit time
No. of channels	1 or 2	1 or 2
Measured parameters	Mean flow value and flow volume patterns	Mean flow value + "instantaneous value"
Simulated Doppler sound	Yes	No
Type of probes	Perivascular, cardiac output and tubing measurements	Perivascular, cardiac output and tubing measurements
Perivascular probe design	Flat Front Face Design	Angular Front Face Design
Probe sizes	1.5mm – 35mm 1/8" – 1/2"	6mm, 32mm 3/8" (Whole range of probes added later)
Probe accuracy	Perivascular: $\pm 10\%$ Cardiac output: $\pm 15\%$ Tubings: $\pm 5\%$	Perivascular: $\pm 10\%$ Cardiac output: $\pm 15\%$ Tubings: $\pm 5\%$
Probe sterilization methods	Ethylene Oxide Gas (ETO), formaldehyde, Steris, J & J Sterrad, or 5% buffered glutaraldehyde	ETO or standard/cold liquid sterilization
Probe count limitation	Yes	No

Medi-Stim Butterfly Flowmeter vs. the predicate device		
	The Medi-Stim Butterfly Flowmeter	Transonic Flowmeter
4. Pressure measurements		
Intended use	Intraoperatively during surgery	None
Technology	Commercial available disposable pressure transducers	N/A
Alarm settings	No	N/A
5. Derived parameters		
Flow parameters		
Pulsatility Index	Yes	No
Instant Q value	Yes	No
Flow integral	Yes	No
Vascular resistance	Yes	No
Auxiliary input	Yes	No
6. User interface		
Flow probe zero line calibration	Automatic (EEPROM)	Manual
Controls	Touch screen or keyboard	Push-button
Read-out	Active matrix 13" display	LED display + analog meter
Documentation	Patient database (hard disk) or print-out	None
7. Technology platform		
Hardware	Pentium microprocessor Proprietary digital transit time front end	Proprietary analog transit time front end and dedicated electronics
Software	Windows '95 and software developed in C++	All algorithms programmed in hardware
8. Acoustic Output	MI < 0,022 Ispta < 0,189 mW/cm ² Isppa < 0,0462 W/cm ² Isata < 0,0833 Isata below pre-amendment level ? Yes	MI < 0,033 Ispta < 0,53 mW/cm ² Isppa < 0,028 W/cm ² Isata N/A Isata below pre-amendment level ? Yes

Table 16. The Medi-Stim Butterfly Flowmeter vs. the predicate device



SEP 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jon H. Hoem, VP International Sales & Marketing
Medi-Stim AS
P.O. Box 35 Grefsen, N-0409
Sandakervein 110, N-0475
Oslo
NORWAY

Re: K992305
Medi-Stim Butterfly Flowmeter:
Models BF1000 BF2000 BF1001 BF2001 BF1004 BF2004 and BF2004
Regulatory Class: II
21 CFR 892.1570/ Procode: 90 ITX, Diagnostic Ultrasound Transducer
21 CFR 870.2100/ Procode: 74 DPT, Cardiovascular Blood Flow-meter
21 CFR 870.2120/ Procode: 74 DPW, Extravascular Blood Flow Probe
21 CFR 870.1110/ Procode: 74 DSK, Blood Pressure Computer
Dated: July 2, 1999
Received: July 8, 1999

Dear Mr. Hoem:

We have reviewed your Section 510(k) 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 transducer intended for use with the Medi-Stim Butterfly Flowmeters, models: BF1000 Single channel flowmeter, BF2000 Dual channel flowmeter, BF1001 Single channel flowmeter with AUX/ECG channel, BF2001 Dual channel flowmeter with AUX/ECG channel, BF1004 Single channel flowmeter with 2 pressure channels and two AUX/ECG channels, and the BF2004 Dual channel flowmeter with 2 pressure channels and two AUX/ECG channels, as described in your premarket notification:

Transducer Model Numbers

PJ100011 1.5mm	PB100041 4mm	PB100082 8mm	PA100271 27mm
PA100021 2mm	PA100042 4mm	PA100121 12mm	PB100271 27mm
PB100021 2mm	PB100042 4mm	PB100121 12mm	PR100151 15mm
PA100022 2mm	PA100051 5mm	PA100122 12mm	PR100181 18mm
PB100022 2mm	PB100051 5mm	PB100122 12mm	PR100211 21mm
PA100031 3mm	PA100052 5mm	PA100161 16mm	PR100251 25mm
PB100031 3mm	PB100052 5mm	PB100161 16mm	PR100301 30mm
PA100032 3mm	PA100081 8mm	PA100211 21mm	PR100351 35mm
PB100032 3mm	PB100081 8mm	PB100211 21mm	
PA100041 4mm	PA100082 8mm		

PII00181 InLine probe, 1/8"	PC100141 ClampOn probe, 1/4", 1/32" wall
PII00141 InLine probe, 1/4"	PC100142 ClampOn probe, 1/4", 1/16" wall
PII00381 InLine probe, 3/8"	PC100382 ClampOn probe, 3/8", 1/16" wall
PII00121 InLine probe, 1/2"	PC100383 ClampOn probe, 3/8", 3/32" wall
PC100181 ClampOn probe, 1/8", 1/32" wall	PC100122 ClampOn probe, 1/2", 1/16" wall
PC100182 ClampOn probe, 1/8", 1/16" wall	PC100123 ClampOn probe, 1/2", 3/32" wall
PC103161 ClampOn probe, 3/16", 1/32" wall	PC100124 ClampOn probe, 1/2", 1/8" wall
PC103162 ClampOn probe, 3/16", 1/16" wall	

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

Page -3- Mr. Hoem

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for 

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form

**PJ100011 1.5mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PJ100011 1.5mm Medi-Stim transit-time probe without handle (J-reflector)
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

(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)

David G. Egan
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

PC100181, PC100182, PC103161, PC103162, PC100141, PC100142, PC100382, PC100383, PC100122, PC100123, PC100124: 1/8", 3/16", 1/4", 3/8" and 1/2" ClampOn Medi-Stim transit-time probe (to be used with BF1000 – BF2004)

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										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										N

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

Additional Comments: PC100181, PC100182, PC103161, PC103162, PC100141, PC100142, PC100382, PC100383, PC100122, PC100123, PC100124: 1/8", 3/16", 1/4", 3/8" and 1/2" ClampOn Medi-Stim transit-time probe; interfaced with a transit-time volume flowmeter for volume flow measurements in tubings. Placed around tubings.

(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 Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PI100181, PI100141, PI100381, PI100121: 1/8", 1/4", 3/8" and 1/2" InLine Medi-Stim transit-time probe
(to be used with BF1000 – BF2004)**

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										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										N

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

Additional Comments: PI100181, PI100141, PI100381, PI100121: 1/8", 1/4", 3/8" and 1/2" InLine Medi-Stim transit-time probe; interfaced with a transit-time volume flowmeter for volume flow measurements in tubings. Spliced into tubings - not for clinical use.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seeger
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PR100151, PR100181, PR100211, PR100251, PR100301 and PR100351
15mm, 18mm, 21mm, 25mm, 30mm and 35mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PR100151, PR100181, PR100211, PR100251, PR100301 and PR100351: 15mm, 18mm, 21mm, 25mm, 30mm and 35mm Medi-Stim transit-time probe without handle; interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular, vascular and transplantation surgery.

(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)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K092305

Diagnostic Ultrasound Indications for Use Form

**PA100271 and PB100271 27mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100271 and PB100271 27mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100211 and PB100211 21mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100211 and PB100211 21mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Beyers
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100161 and PB100161 16mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100161 and PB100161 16mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David C. Hegeman
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100122 and PB100122 12mm Medi-Stim transit-time probe with handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100122 and PB100122 12mm Medi-Stim transit-time probe with handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David W. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100121 and PB100121 12mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100121 and PB100121 12mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Peterson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100082 and PB100082 8mm Medi-Stim transit-time probe with handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100082 and PB100082 8mm Medi-Stim transit-time probe with handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David L. Seligson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100081 and PB100081 8mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100081 and PB100081 2mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Bergman
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100052 and PB100052 5mm Medi-Stim transit-time probe with handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100052 and PB100052 5mm Medi-Stim transit-time probe with handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

[Signature]
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number E992305

Diagnostic Ultrasound Indications for Use Form

**PA100051 and PB100051 5mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100051 and PB100051 5mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segerson
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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100042 and PB100042 4mm Medi-Stim transit-time probe with handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100042 and PB100042 4mm Medi-Stim transit-time probe with handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segerson
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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number R992305

Diagnostic Ultrasound Indications for Use Form

**PA100041 and PB100041 4mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100041 and PB100041 4mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David L. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100032 and PB100032 3mm Medi-Stim transit-time probe with handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100032 and PB100032 3mm Medi-Stim transit-time probe with handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David C. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100031 and PB100031 3mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: PA100031 and PB100031 3mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100022 and PB100022 2mm Medi-Stim transit-time probe with handle
(to be used with BF1000 – BF2004)**

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

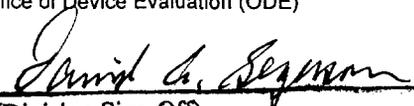
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										N
Intraoperative Neurological										
Pediatric							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

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

Additional Comments: PA100022 and PB100022 2mm Medi-Stim transit-time probe with handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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Prescription Use (Per 21 CFR 801.109)


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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**PA100021 and PB100021 2mm Medi-Stim transit-time probe without handle
(to be used with BF1000 – BF2004)**

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

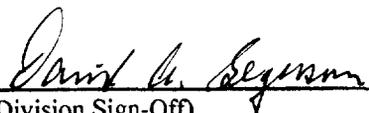
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										N
Intraoperative Neurological										
Pediatric							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

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

Additional Comments: PA100021 and PB100021 2mm Medi-Stim transit-time probe without handle;
interfaced with a transit-time volume flowmeter for volume flow measurements during cardiovascular,
vascular and transplantation surgery.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K992305

Diagnostic Ultrasound Indications for Use Form

**Medi-Stim Butterfly Flowmeter
 BF1000 Single channel flowmeter
 BF2000 Dual channel flowmeter
 BF1001 Single channel flowmeter with AUX/ECG channel
 BF2001 Dual channel flowmeter with AUX/ECG channel
 BF1004 Single channel flowmeter with 2 pressure channels and two AUX/ECG channels
 BF2004 Dual channel flowmeter with 2 pressure channels and two AUX/ECG channels**

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)										N
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: Medi-Stim Butterfly Flowmeter BF1000 – BF2004; transit-time volume flowmeter; volume flow measurements during cardiovascular, vascular and transplantation surgery.

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 Concurrence of CDRH/Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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 510(k) Number K992305