

K972798

10. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

FEB 24 1998

A. Submitter Information

Sponsor: SOMETEC, Inc.
c/o Interactive Consulting Inc.
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Wellesley, MA 02181
(617) 239-8108
(617) 674-2002 Fax

Manufacturer: SOMETEC
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75012 Paris, FRANCE

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Contact Person: Jean-Luc Boulnois, Ph.D.
President

Date Prepared: July 17, 1997

B. Device Identification

Common/Usual Name Aortic Blood Flow Monitor
Proprietary Name: DYNEMO 3000

C. Identification of Predicate Device(s)

The DYNEMO 3000 is substantially equivalent to the following previously cleared and currently marketing devices:

Hewlett Packard HP 21362B (K884395)
Datascope ACCUCOM (K851426)
Deltex EDM (K951369)

D. Device Description

The DYNEMO 3000 is a non-invasive hemodynamic diagnostic device designed to provide the anesthesiologist, cardiologist, and intensive care physician with a non-invasive continuous hemodynamic profile derived from measurement and monitoring of the aortic blood flow (ABF) in real time. The DYNEMO 3000 is designed to operate in a clinical setting in which an adult or pediatric patient is under anesthesia and/or in intensive care. This type of monitoring device also offers the anesthesiologist and intensive care physician the capability of tracking critical parameters providing indications on the patient's cardiovascular status.

The DYNEMO 3000's principle of operation is based on the simultaneous, real-time ultrasound measurement of aortic diameter and blood velocity, independently. This is achieved by inserting an endo-esophageal (or transesophageal) probe equipped with two (2) ultrasonic transducers is inserted into the patient's esophagus either trans-orally or trans-nasally.

The measurement of the descending aortic diameter is made through M-Mode echo ultrasonography at a 10 MHz frequency. A thin beam resulting from the 10

000117

MHz ultrasonic wave, produces high resolution images of the aortic walls. Through the manual rotation of the probe's distal end by the user, the M-Mode signal can be optimized, thereby providing an accurate measurement of the instantaneous aortic diameter.

A second transducer measures the Doppler signal. The 5 MHz Doppler velocimeter allows for the precise velocity measurement over the section of the aorta.

These two (2) ultrasound measurements are combined in real-time to provide an accurate measurement of the aortic blood flow (ABF) in the descending aorta. The microprocessor based DYNEMO 3000 unit communicates with external peripheral monitors including ECG, non-invasive blood pressure, and capnograph. A specialized software then synchronously combines data with that from these peripheral monitors to continuously display the composite hemodynamic profile of the patient in real time:

- Aortic blood flow,
- Arterial pressures,
- Heart rate,
- Stroke volume in aorta,
- Total systemic vascular resistance for aortic circuit
- Systolic time intervals, and,
- End-tidal CO2 pressure.

The DYNEMO 3000 consists of five primary components:

- the main console,
- the transesophageal probe,
- the disposable silicone sheath including an inflatable balloon,
- the probe support, and,
- the probe cable.

The main console provides various indicators and controls designed to lead the operator through the sequential procedures needed for the operation of the DYNEMO 3000 device. It contains a 7" screen used to display the parameters and the charts associated with the patient's ABF measurement. The console also houses the electrical components, and a data recording unit. The device operates from a 100-240V supply.

The adult and pediatric transesophageal probe is comprised of a flexible "insertion tube", a sensor tip, and a mechanical head.

The flexible "insertion tube" is used for mechanical and electrical connection between the mechanical head and the sensors. It is fitted with a sliding O ring indicator to mark the depth of insertion. A cable located inside of the insertion tube can rotate along its axis without movement of the outer casing.

The sensor tip, comprises of two (2) piezo-electric transducers.

The mechanical head rotates axially with an index that moves in front of another reference index located on the fixed section. This constitutes the orientation mechanism of the ultrasound transducers. A fixed section supports a lock and tap for filling and emptying a silicone balloon sheath. This section also permits to lock the transesophageal probe to the flexible probe support.

A single-use, disposable adult or pediatric balloon sheath is chosen according to the selected probe, and the transesophageal probe is inserted inside the balloon sheath which then covers the entire probe, including the sensor tip. When filled with de-mineralized water, the balloon sheath inflates up to the esophageal wall, immobilizes the probe into the esophagus, directs the ultrasound sensors to the aortic target, and guarantees a parallel positioning between the sensor sub-assembly and the axis of the aorta.

The mechanical head of the transesophageal probe remains fixed adjacent to the patient's head and is locked to the patient's operating table or bed with a probe support.

E. Substantial Equivalence

The technical characteristics are almost identical to those of the Hewlett Packard HP21362B (K884395), the Datascope ACCUCOM (K851426), and the Deltex EDM (K951369) previously cleared predicate devices. Refer to Tables A, B, and C for a comparison of these predicate devices. Differences that exist between these devices in terms of technical specifications, ultrasonic technology, functions, performances, intended use, and methods of application, do not affect the relative safety or effectiveness of the DYNEMO 3000 device.

The intended use for the DYNEMO 3000 device, as with the previously cleared devices, is to provide the anesthesiologist, cardiologist and intensive care physician with

- a non-invasive, continuous real-time measurement and monitoring of the aortic blood flow for adult or pediatric patients under anesthesia and/or in intensive care;
- The derivation of real-time composite hemodynamic profile providing indications on the patient's cardiovascular status.

The composite hemodynamic profile consists of the following:

- Aortic blood flow,
- Arterial pressures,
- Heart rate,
- Stroke volume in the aorta,
- Total Systemic vascular resistances for aorta circuit,
- Systolic time intervals, and,
- End-tidal CO2 pressure.

TABLE A: Equivalence Table: Performance Data
Non-Invasive Transesophageal Pulsed Doppler and Echographic Devices

	HewlettPackard HP 20382B	Datacube ACCH001	Deltex EDM	Sometec DYNEMO 3000
Transesophageal probe				
Adult probe length (cm)	100	76	80	61
Adult probe diameter (mm)	9.8	7.9	6	7
Distal tip diameter (mm)	11.0	7.9	6	7
Pediatric probe length (cm)	100	No pediatric probe	No pediatric probe	35
Pediatric probe diam. (mm)	9.8 size permitting	-	-	5
Distal tip diameter (mm)	11.0	-	-	5
Pulsed Doppler Transducer				
Center frequency (MHz)	5	2.5	4	5
Pulse duration (μ s)	0.74	34	17	11
Entry beam diameter (mm)	10	6.0	-	4
Pulse rep. frequency (kHz)	12.9	5.9	Continuous	12.4
Intensity I_{SPTA} (mW/cm ²)	184	100	100	165
M-mode Echograph				
Center frequency (MHz)	5	None	None	10
Pulse duration (μ s)	0.28			0.225
Entry beam diameter (mm)	10			3
Pulse rep. frequency (Hz)	3.9			46.9
Intensity I_{SPTA} (mW/cm ²)	35			<1
Measurement Ranges				
Adult Probe				
Blood Flow Velocity (cm/sec)	Not available	10-300	10-220	10-196
Aortic Diameter (mm)		None	None	7.9-48
Cardiac Output (l/min)		0-20	0-20 estimated	Not measured
Aortic Blood Flow (l/min)		-	-	0.3-20
Pediatric Probe				
Blood Flow Velocity (cm/sec)	Not available	None	None	10-196
Aortic Diameter (mm)				3-36
Cardiac Output (l/min)				Not measured
Aortic Blood Flow (l/min)				0-20

TABLE B: Equivalence Table: Technical Features
Non-Invasive Transesophageal Pulsed Doppler and Echographic Devices

	Hewlett Packard HP 21362B	Datascope ACCUCOM	Deltex EDM	Sometec DYNEMO 3000
Transesophageal probe Flexible shaft Adult probe sheath Pediatric probe sheath Sheath material Positioning balloon Rotatable transducer(s)	Yes Recommended - Latex No - Yes	Yes No - No - No: entire probe	Yes Single use probe - No - No: entire probe	Yes Single use sheath Single use sheath Silicone Yes Adult ϕ 18 mm Pediatric ϕ 8/12 mm Yes
Operating Mode Continuous flow monitor Single beat measurement Cardiac Output calibration Aortic diameter Blood pressure input ECG signal input End-tidal CO2 input	Yes Yes None M-mode measurement	Yes Yes By suprasternal notch/ By entering known CO Nomogram (height, weight, age, sex) Automatic or manual None None None	Yes - Nomogram (height, weight, age, sex) None None None	Yes No - M-mode measurement - Automatic Automatic Automatic
Display Ranges Heart Rate Sensing (b/mn) Flow Velocity (cm/sec) Cardiac Output (l/min) Aortic Blood Flow (l/mn) Stroke Volume (ml) aorta Mean blood pressure(mm/Hg) Systemic vascular resistance Systolic time intervals	Not available	30-200 10-300 0-20 - 0-300 External monitor range 0-9990	30-200 10-220 0-20 estimated - 0-300 estimated External monitor range - Flow time/ Peak velocity	34-230 10-117 - 0-20 3-150 35-240 300-15000 PEPi: 75-240 LVETi: 250-600
Screen display Doppler signal trace Aortic walls separation trace Composite numerical hemodynamic profile Parameter trends Doppler audio confirmation Color screen Patient analysis software	Yes Yes - - Yes	Yes No HR, CO, CI, LVET TSVR - No No Monochrome No	Yes No HR, CO, SV, MAP Flow time Peak velocity Accelrtn Yes Yes Color No	Yes Yes HR, ABF, Sva, ABP, TSVR, PEPi, LVETi PetCO2, Diam. Yes Yes Monochrome DYNESOFT

TABLE C: Equivalence Table: Clinical Characteristics
Non-Invasive Transesophageal Pulsed Doppler and Echographic Devices

	Hewlett Packard HP 21362B	Datascope ACCUCOM	Deltex EDM	Sometec DYNEMO 3000
Transesophageal probe				
Target	Heart & vessels	Aorta	Aorta	Aorta
Measured parameter(s)	Blood flow velocities in heart & vessels Anatomic physiologic parameters of heart & vessels	Cardiac Output	Cardiac Output	Aortic Blood Flow
Patient population Adults/ Pediatrics	Adults and Pediatrics (size permitting)	Adults	Adults	Adults & Pediatrics
Patient status	Anesthetized patients Awake patients	Anesthetized patients ICU patients	Anesthetized patients High risk patients Critically ill patients	Anesthetized patients ICU patients
Intended Use	Non-invasive cardiac studies	Non-invasive, continuous cardiac output monitoring	Non-invasive, cardiac function monitoring	Non-invasive, continuous aortic blood flow monitoring
Contraindications	Existing gastro- esophageal abnormalities	Esophageal abnormalities	Esophageal abnormalities	Oro-pharyngeal malformations Esophageal distortions Aortic coarctation Esophageal carcinoma



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jean-Luc Boulnois, Ph.D.
President & CEO
Sometec, Inc.
92 Montvale Avenue-Suite 3150
Stoneham, MA 02180

FEB 24 1998

Re: K972798
DYNEMO 3000 (Cardiac Output Monitor)
Dated: November 24, 1997
Received: November 25, 1997
Regulatory class: II
21 CFR 870.2100/Procode: 74 DPW
21 CFR 870.2300/Procode: 74 DPT

Dear Dr. Boulnois:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DYNEMO 3000 Cardiac Output Monitor, as described in your premarket notification:

Transducer Model Number

Adult Model 200-018
Pediatric Model 200-019

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.

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 **Rodrigo C. Perez** at (301) 594-1212.

Sincerely yours,

for David L. DeFranco
Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972798

Device Name: **DYNEMO 3000**

Indications for Use:

1. Adults (Transesophageal Probe Model 200-018)

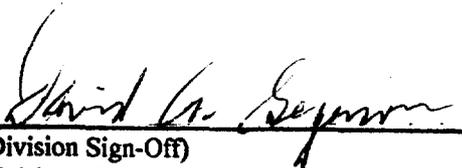
- Non-invasive, continuous, real-time measurement and monitoring of the aortic blood flow for adult patients under anesthesia and/or in intensive care.
- Derivation of real-time composite hemodynamic profile (aortic blood flow, arterial pressures, heart rate, stroke volume in the aorta, end-tidal CO₂ pressure, systemic vascular resistances for aortic circuit, systolic time intervals), providing indications of cardiovascular status.

2. Pediatrics (Transesophageal Probe Model 200-019)

- Non-invasive, continuous, real-time measurement and monitoring of the aortic blood flow for pediatric patients under anesthesia and/or in intensive care.
- Derivation of real-time composite hemodynamic profile (aortic blood flow, arterial pressures, heart rate, stroke volume in the aorta, end-tidal CO₂ pressure, systemic vascular resistances for aortic circuit, systolic time intervals), providing indications of cardiovascular status.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972798

Prescription Use /
(Per 21 CFR 801.109)

OR

Over-the Counter Use _____

(Optional Format 1-2-96)

510(k) Number (if known): K972798
 Device Name: DYNEMO 3000 (Adult Model 200-018)

Fill out one form for each ultrasound system and each transducer.

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac			X							
Trans-esophageal			X							
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

Additional Comments: _____

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Concurrence of CDRE, 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 K972798

510(k) Number (if known): K972798

Device Name: DYNEMO 3000 (Pediatric Model 200-019)

Fill out one form for each ultrasound system and each transducer.

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac				X						
Trans-esophageal				X						
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

Additional Comments: _____

(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 Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K972798

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