JUN 3 0 2003

K024323

510(k) Summary of Safety and Effectiveness

Submitter	Biomedical Systems Corporation 2464 West Port Plaza Drive St. Louis, MO 63146 Phone: 314-576-6800 FAX: 877-286-8141
Contact person	K. Michael Kroehnke Director, Quality Assurance/Regulatory Affairs
Date of preparation	December 20, 2002
Device trade name	Century Series ™ Holter Scanner System Model C3000/C2000/C1000
Common or usual name	Holter ECG analysis software
Classification name	Medical Magnetic Tape Recorder
Product classification	74 MLO, 21 CFR 870.2800, Class II
Predicate Device	Century Color Trace (K884152, Biomedical Systems)
Device Description	The Century Series Holter Scanner System, Model C3000/C2000/C1000 is a Holter ECG analysis software application that allows evaluation of Holter recordings obtained using solid-state digital Holter recorders or standard cassette tape Holter recorders. It is the successor to the Century Color Trace Holter Analyzer, 510(k) # K884152. The analysis is based on the WPI algorithm, as was the Century Color Trace. The unit features arrhythmia analysis, ST deviation analysis, pacemaker beat detection, and determination of beat types, in both an automatic and interactive mode.
Intended use	The Century Series Holter Scanner System, Model C3000/C2000/C1000 is intended for the replay and analysis of ECG data pre-recorded on compatible cassette tape or digital Holter recorders and is

indicated for:

- Cardiac evaluation of heart rate and rhythm in patients experiencing syncope, near syncope, dizziness, palpitations, shortness of breath, chest pain and transient arrhythmias.
- To assess risk for future cardiac events in patients without symptoms from arrhythmia who have bee diagnosed with congestive heart failure, idiopathic hypertrophic cardiomyopathy, and post myocardial infarction with left ventricular dysfunction.
- Assessment of drug response in patients taking antiarrhythmic medications. Baseline frequency of the arrhythmia should be characterized as reproducible and of sufficient frequency to permit evaluation.
- ST segment analysis in patients with known coronary heart disease, chest pain, and suspected variant angina.

Patient population: human beings without restrictions of age, sex, or race requiring analysis of 24 hour ambulatory ECG recordings as determined by a medical practitioner.

Caution: Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.

Table of Comparison:

	Century Color Trace	**Century Series C3000**	**Century Series C2000**	**Century Series C1000**
Recording medium	Reel-to-Reel tape or tape cassette	Digital recorder or tape cassette	Digital recorder or tape cassette	Digital recorder or tape cassette
Channels	2	3	3	3

System Requirements				
CPU	80386 20 MHz 4 MB RAM 80 MB hard drive	Pentium 300 MHZ 128 MB RAM 4 GB hard drive	Pentium 300 MHZ 128 MB RAM 4 GB hard drive	Pentium 300 MHZ 128 MB RAM 4 GB hard drive
Operating System	MS-DOS 3.3	MS Windows 98, 2000, XP	MS Windows 98, 2000, XP	MS Windows 98, 2000, XP
Monitor	13" color	15" SVGA	15" SVGA	15" SVGA
Printer	Laser	Same	Same	Same
Software				
Analysis algorithm	WPI	Same	Same	Same
Analysis Modes				
Automated Analysis	Yes	Yes	Yes	Yes
Retrospective Superimposition	Yes	Yes	Yes	Yes
Prospective Superimposition	Yes	Yes	Yes	n/a
Prospective Superimposition w/ Editing	Yes	Yes	N/a	n/a
Full Disclosure	Yes	Yes	Yes	Yes
Customized Report	Yes	Yes	Yes	Yes
Remote Transmission Capability	Yes	Yes	Yes	Yes
ST segment analysis	Yes	Yes	Yes	Yes
QRS detection/arrhythmia analysis	Yes	Yes	Yes	Yes
HRV-time domain analysis	No	Yes	Yes	Yes
QT analysis	No	Yes	Yes	Yes
Pacemaker evaluation display	Yes	Yes	Yes	Yes
Ventricular ectopy summary	Yes	Yes	Yes	Yes
Bradycardia table	Yes	Yes	Yes	Yes
ST Trend	Yes	Yes	Yes	Yes
Strip List	Yes	Yes	Yes	Yes
Supraventricular ectopy summary	Yes	Yes	Yes	Yes
Ventricular tachycardia summary	Yes	Yes	Yes	Yes
VE pair summary	Yes	Yes	Yes	Yes
Bigeminy summary	Yes	Yes	Yes	Yes

Target Population	Humans without restrictions of age, sex, or race requiring ambulatory ECG as determined by a medical practitioner	Same	Same	Same
Where Used	Physician office, clinic, hospital	Same	Same	Same

The primary differences between the Century Color Trace and the Century Series Holter Scanner System, Model C3000/C2000/C1000 are the microprocessor speed - 386 vs. Pentium, the addition of the HRV-Time Domain and QT analysis modules and the migration from the MS-DOS operating system to the MS Windows™ operating system.

These differences do not, however, represent a change of the intended use(s) and indications of the Century Series Holter Scanner System, Model C3000/C2000/C1000 from those described for the Century Color Trace, or alter the fundamental technology of the Holter analysis as described for the Century Color Trace.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2003

Biomedical Systems Corporation
c/o Mr. K. Michael Kroehnke
Director, Quality Assurance/Regulatory Affairs
2464 West Port Plaza Dr.
St. Louis, Missouri 63146

Re: K024323
Trade Name: Century Series™ Holter Scanner System, Model C3000/C2000/C1000
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MLO
Dated: April 1, 2003
Received: April 2, 2003

Dear Mr. Kroehnke:

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.

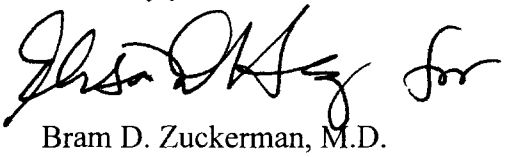
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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 Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K024323

Intended Use

The Century Series Holter Scanner System, Model C3000/C2000/C1000 is intended for the replay and analysis of ECG data pre-recorded on compatible cassette tape or digital Holter recorders and is indicated for:

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Prescription Use Only

Prescription Use ✓

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024323