

K983582

NOV 13 1998



TECHNOLOGY SOLUTIONS  
FOR MEDICINE



Certificate Number EM30381

**510(k) Summary  
for  
Meridian Medical Technologies Ltd  
CardioBeeper® CB250**

**Submitter**

Name and Address

Meridian Medical Technologies Ltd  
Enkalon Industrial Park,  
25 Randalstown Road,  
Antrim,  
BT41 4LJ  
Northern Ireland

Tel:

+ 44 1849 465314

Fax:

+ 44 1849 428192

Contact Name

Gerard Lynn  
Regulatory Affairs Manager

Date of Application

October 7<sup>th</sup> 1998

**Device Name**

Trade Name:

CardioBeeper® CB250

Classification Name:

Telephone electrocardiograph transmitter and receiver per  
21 CFR 880.2920

Meridan Medical Technologies Ltd.

Enkalon Industrial Estate,

25 Randalstown Road,

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Phone: 01849 465314

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Company Reg. No. N.I. 20416

CardioBeeper® CB250 510(k) Notification



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Certificate Number EM10383

### Substantially Equivalent Devices

The CardioBeeper® CB250 is substantially equivalent to other telephone electrocardiograph transmitters that have received 510(k) clearance for use by the patient in transmitting ECG information from a remote location to a receiving center.

Specifically, the CardioBeeper® CB250 is used in a similar manner to the CardioBeeper® CBII (K883843), and it shares some, but not all, of the functions of the CardioBeeper® CB II (K883843) and the CardioBeeper® CB12-L (K965101).

The CardioBeeper® CB250 is substantially equivalent to a CardioBeeper® CBII (K883843) in Mode 1 (modified single channel). Both units have fixed electrodes and both transmit a real-time rhythm strip. The CardioBeeper® CB250 uses a reduced set of the electronic circuitry of the CardioBeeper® CB II (K883843) and the CardioBeeper® CB12-L (K965101). The main differences are:

- the lead selection logic has been removed from the CardioBeeper®CB12L
- surface mount and low-profile components have been used in the CardioBeeper® CB250 to allow the entire device to fit inside a bill-fold wallet.

	CardioBeeper® CB250	CardioBeeper® CB12L	CardioBeeper® CBII
Batteries:	Two 3V LiMno2 cells	9Vdisposable alkaline	9Vdisposable alkaline
Current Drain:	7mA max	18mA max	18mA max
Expected life:	>3 years in normal operation	Approx 1 year until batteries need replaced	Approx 1 year until batteries need replaced
Operating Range:	5 to 50 degrees C, <80%RH	+10 to +40° C 30% to 70% RH	+10 to +40° C 30% to 70% RH
<b>Amplifier:</b>			
CMRR:	80dB min	80dB min	80dB, min
Frequency Response:	0.05 to 150 Hz	0.05Hz to 150Hz	0.05Hz – 35Hz
System noise:	<40µV r.t.i.	<40µV r.t.i.	<40µV r.t.i.
<b>FM Output:</b>			
Center Frequency:	1700±20Hz	1700±20Hz	1700Hz±20Hz
Sensitivity	127.5 Hz/mV ±5%	127.5 Hz/mV ±5%	127.5 Hz/mV ±7.5%
Transmissions:	Modified Lead 1 (real time)	Modified Lead 1 (real time)	Modified Lead 1 (real time); Rolling loop

**Comparison of CardioBeeper® CB250 and substantially equivalent devices**



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### Description of the Device

The CardioBeeper ® CB250 is a single-lead, compact, hand-held, battery powered, personal transtelephonic ECG transmitter enclosed in a billfold wallet. The device has been designed to enable the user to transmit a rhythm strip to a central receiving station using acoustic coupling. The ECG information is transmitted as a frequency modulation of the basic 1700Hz tone. The device is sealed (not hermetically) for life. There are no user-servicable parts inside. The batteries are not replaceable and the unit should be discarded after depletion.

### Intended Use of the Device

The CardioBeeper ® CB250 is intended to condition an electrocardiographic signal so that it can be transmitted via telephone to a remote location. The CardioBeeper ® CB250 is designed to be incorporated in a custom wallet to be used by a patient to transmit a rhythm strip in realtime to a physician's office, hospital or other medical receiving center. The device has permanently attached re-useable dry silver electrodes.

CardioBeeper ® is a registered trademark of Meridian Medical Technologies Inc.

Meridan Medical Technologies Ltd.  
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Antrim, Co. Antrim BT41 4LJ  
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CardioBeeper ® CB250 510(k) Notification



NOV 13 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Gerard Lynn  
Manager, Regulatory Affairs  
Meridan Medical Technologies Ltd.  
Enkalon Industrial Estate  
25 Randalstown Road  
Antrim, Co. Antrim BT41 4LJ

Re: K983582  
CardioBeeper® CB250  
Regulatory Class: II (two)  
Product Code: 74 DXH  
Dated: October 7, 1998  
Received: October 13, 1998

Dear Mr. Lynn:

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.

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21CFR 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K983582

DEVICE NAME: CARDIOBEEPER CB250

INDICATIONS FOR USE:

THE CARDIOBEEPER CB250 IS INDICATED FOR USE BY THE PATIENT IN TRANSMITTING ECG INFORMATION FROM A REMOTE LOCATION TO A RECEIVING CENTER.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

(Division Sign Off)  
Division of Respiratory  
and Devices  
510(k) Number K983582