APR - 7 2004

510(k) SUMMARY

Submitted For:	Bio Protech Inc. 1720-26, Wonju Medical Instrument Industry Park Taejang-2 dong, Wonju-si, Gangwon-do Korea
Submitted by:	E. J. Smith Smith Associates PO Box 4341 Crofton, MD 21114
Date of Submission:	January 16, 2004
Classification Name:	Electrode, Electrocardiograph Product Code DRX Class II Device
Proprietary Name:	PROTAB ECG TAB ELECTRODE
Common Name:	ECG Electrode
Regulatory Reference:	CFR 870.2360
Predicate Device:	Bio Protech, Inc. Telectrode ECG Electrode K020003 Leonard Lang GmbH Skintact® ECG Tab Electrode K030509
Intended Use:	PROTAB ECG Tab Electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include patient ECG surveillance and ECG diagnosis recording. PROTAB ECG Tab Electrodes are non-sterile and are to be used on intact (uninjured) skin.
Description:	ECG Tab electrodes are composed of a PET tape, Ag/AgCl

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	ink and a conductive gel. These are configured as 10 (ten) electrodes applied to a siliconized transparent PET card, ten cards per pouch.
Substantial Equivalence:	PROTAB ECG Tab Electrodes with solid adhesive gel are substantially equivalent to the PROTABECG Tab Electrodes with Skintact@ ECG Tab Electrodes (the manufacturer's predicate - K030509). The Ag/AgCl ink layer added for performance is substantially equivalent to the Bio Protech PRO TECH electrode K020003.
Performance Summary:	PROTAB ECG Tab Electrodes have been tested and conforms to ANSI/AAMI EC12:2000
Biocompatibility Testing:	The biological safety of the PROTAB ECG Tab electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The tests were selected on the basis of ISO 10993-1, Biological Evaluation of Medical Devices – Part 1 – Guidance on selection of tests.
Shelf Life:	Accelerated aging testing was performed to substantiate an expiration of 24 months.
Conclusion :	This device is substantially equivalent to the devices approved as K020003 and K030509

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Bio Protech, Inc.
c/o Mr. Ned Devine
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K040784
Trade Name: PROTAB ECG TAB ELECTRODE
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: January 21, 2004
Received: March 29, 2004

Dear Mr. Smith:

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) 594-4648. 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

K040784

Indications for Use

510(k) Number (if known): K040784

Device Name: PROTAB ECG TAB ELECTRODE

Indications for Use:

PROTAB ECG Tab Electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician.

Such procedures include patient ECG surveillance and ECG diagnosis recording. PROTAB ECG Tab Electrodes are non-sterile and are to be used on intact (uninjured) skin.

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

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040784

(Posted November 13, 2003)