K073360

BIO PROTECH, INC.
1720-26, Taejang 2 – Dong, Wonju
Woonju-Si, Gangwon-Do
Republic of South Korea

DEC 19 2007

510(K) Summary

December 12, 2007

Contact: Mr. Kevin Han
17962 Sky Park Circle
Suite G
Irvine, CA 92614
Phone: 310-515-1799

Classification Name:	Electrosurgical, Cutting and Coagulation Device and Accessories
Common/Usual Name:	Electrosurgical Grounding Plate
Proprietary Name:	PROPLATE
Establishment Registration Number:	9710582
Classification:	Class II
Product Code:	GEI
Regulation Number:	21 CFR 878.440

1. Indications for use

The PROPLATE of Bio Protech is a disposable, single use, neutral electrode, which provides a return path for high frequency electrical current to the ESU device.

2. Description of Product

The PROPLATE Electrosurgical Grounding Plate *(and as also to be offered for sale under various private label trade names)* is a flexible, conductive adhesive electrosurgical grounding plate with integrated 3 meter PVC coated cable and standard MSB-female connector. It is an Electrosurgical Grounding Plate at which no electrosurgical effect is intended. It is also known as the patient plate or inactive, indifferent, neutral, return or dispersive electrode. It is frequently, and sometimes inaccurately, referred to as the ground plate. The Electrosurgical Grounding Plate is for use with monopolar instruments only.

The role of the Electrosurgical Grounding Plate is preventing highly current density from doing damage to the patient's tissue. And Electrosurgical Grounding Plate transfer input current from the active electrode to ESU device in operation. The Electrosurgical Grounding Plate is large in area, compared to the active electrode, promoting low current density and thereby reducing the possibility or risk of electrosurgical effect or burns. The PROPLATE is made from conductive hydro gel and aluminum foil. The adhesive on the backing material prevent them from falling off the patient's skin during operation. The plates are supplied either uncorded or corded. The

electrodes are packaged with 100 pieces (Uncorded plates) or 25 pieces (Corded plates) per an inner box. The plates are provided non-sterile with an expiration date of 24 months.

Substantial Equivalent Table:

Parameters			Bio Protech, Inc.	Leonhard Lang GmbH
510(k) Number			Pending	K030362
Intended Use			Electrosurgical grounding plate	Electrosurgical grounding plate
Uncorded			Yes	Yes
Corded			Yes	Yes
Labeling	Latex free		Yes	Yes
	Intended population		Adult and Pediatric	Adult and Pediatric
	Single Use		Yes	Yes
	Non-sterile		Yes	Yes
Material	Plate size		Various sizes	Various sizes
	Substrate		Cloth (Non-woven Fabric) and PE Foam	Cloth (Non-woven Fabric) and PE Foam
	Gel		Sticky conductive gel with thin Aluminum Foil	Sticky conductive gel with thin Aluminum Foil
	Release Liner		PET coated Silicon	PET coated Silicon
	Connector (compatible)		REM (Valleylab)	REM (Valleylab), 6.3mm jack (standard)
	Cable		Blue PVC cable	Blue PVC cable
Biocompatibility			ISO 10993-1	ISO 10993-1
Technical	Maximum safe temperature rise		Pass	Pass
	Contact impedance		Pass	Pass
	Adherence	Pull test	Pass	Pass
		Conformability test	Pass	Pass

		Fluid tolerance test	Pass	Pass

The PROPLATE ahs the same intended use, uses the same material and has the same performance characteristics as the predicate device. Both devices have met the HF-18 requirements for electrical safety both meet ISO 10993 Standards for biocompatibility. Based on the similarities of the two devices Bio Protech concludes that no new issues of safety and effectiveness have been raised and thus it is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2007

Bio Protech, Inc.
% Underwriters Laboratories, Inc.
Mr. Jeff Rongero
Senior Project Engineer
12 Laboratory Drive
Research Triangle, North Carolina 27709

Re: K073360
Trade/Device Name: PROPLATE
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: December 13, 2007
Received: December 14, 2007

Dear Mr. Rongero:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073360

Device Name: PROPLATE

Indications for Use:

The PROPLATE of Bio Protech is a disposable, single use, neutral electrode, which provides a return path for high frequency electrical current to the ESU device.

Prescription Use ____X___ (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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073360