K092732

510(k) Summary
807.92(c)

NOV 25 2009

SPONSOR **807.92(a)(1)**

Company Name:	Bio Protech, Inc.
Company Address	1720-26, Taejang 2 – Dong, Wonju Woonju-Si, Gangwon-Do Republic of South Korea
Telephone:	310-515-1799
Fax:	
Contact Person:	Kevin Han

Summary Preparation Date: March 13, 2009

DEVICE NAME **807.92(a)(2)**

Trade Name:	Propencil ESU Pencil
Common/Usual Name:	Electrosurgical Pencil
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessoriess
Regulation Number:	878.4400
Product Code:	GEI
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Conmed, Inc.	Hand Controlled Electrosurgical pencils	K896626

DEVICE DESCRIPTION **807.92(a)(4)**

The PROPENCIL ESU pencil *(and as also to be offered for sale under various private label trade names)* is intended for standard electrosurgical operation such as cutting and coagulation. It is designed to work with standard electrosurgical generators.

PROPENCIL consists of various types of disposable ESU pencils with hand controlled switch for cutting and coagulation. All of products are sterile device. The method of sterilization is Gamma sterilization. The hand controlled switch is pushbuttons or rocker button and the blade is an uncoated stainless steel electrode or non-stick coated stainless steel electrode.

DEVICE INTENDED USE **807.92(a)(5)**

The PROPENCIL ESU Pencil is intended for use in general surgical procedures to deliver electrosurgical energy to the surgery site for tissue cutting and coagulation.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

Parameters	**Bio Protect Inc.** (PROPENCIL)	**CONMED CORP.** (HAND CONTROLLED ELECTROSURGICAL PENCILS)
510(k) Number	N/A	K896626
Intended Use Statement	The PROPENCIL ESU Pencil is intended for use in general surgical procedures to deliver electrosurgical energy to the surgery site for tissue cutting and coagulation.	The Conmed ESU Pencils are intended for use in general surgical procedures to deliver electrosurgical energy to the surgery site for tissue cutting and coagulation
Styles:		
Button Switch	Yes	Yes
Rocker Switch	Yes	Yes
Smoke Evacuation Unit	No	No
Mode of Operation:		
Mode of Action	Cut and Coagulation	Cut and Coagulation
Tip Configuration(s)	General	General
Biopolar/Monopolar	Monopolar	Monopolar
Materials Used:		
Shell	ABS Resin	ABS Resin
Electrode	SUS 304 1/2H or FEP coated SUS 304 1/2H	Stain less steel
Insulating Material	Thermal Shrinking tube	Silicon tube
Removable Electrode	Yes	Yes
Hard Wire Cable	3m 3p cord (3Φ)	3m 3p cord (3Φ)

Standards:		
IEC 60601-2-2: 2006	Pass	Pass
AAMI HF-18, for Cable Strain Test	Pass	Pass
Sterile	Yes (only a disposable product)	Yes
Single Use	Yes (only a disposable product)	Yes

NONCLINICAL AND CLINICAL TEST **807.92(b)**

SAFETY and EFFECTIVENESS

Safety testing electrical
BioProtech, Inc. tested the PROPENCIL to the following standard:
IEC 60601-2-2:2006 AAMI HF18:2001 Cable Strain Relief Test

CONCLUSION **807.92(b)(3)**
PROPENCIL Electrosurgical Pencil is similar to the predicate device in

- intended use,
- materials and
- design.

The PROPENCIL Electrosurgical Pencil introduces no new questions concerning safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Bio Protech, Inc.
% Underwriters Laboratories Inc.
Mr. Ned Devine
333 Pfingsten Road
Northbrook, IL 60062

NOV 2 5 2009

Re: K092732
Trade/Device Name: Propencil Electrosurgical Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: November 11, 2009
Received: November 12, 2009

Dear Mr. Devine:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Propencil Electrosurgical Pencil (also offered for sale under various private label trade names)

Indications for Use:

The PROPENCIL ESU Pencil is intended for use in general surgical procedures to deliver electrosurgical energy to the surgery site for tissue cutting and coagulation.

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)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092732