



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 8, 2016

I.C. Medical, Inc.  
Elena Buiga  
Director of RA/QA/ISO  
2340 W. Shangri La Rd.  
Phoenix, Arizona 85029

Re: K160160

Trade/Device Name: Non-Telescopic PenEvac  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: January 25, 2016  
Received: January 27, 2016

Dear Elena Buiga:

This letter corrects our substantially equivalent letter of April 5, 2016.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

**Jennifer R. Stevenson -A**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160160

Device Name

Non-Telescopic PenEvac

Indications for Use (Describe)

The PenEvac® is intended to be used as the active Monopolar electrode in an electrosurgery generator system and to facilitate the removal of smoke that is generated during procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

### Submitter/Holder:

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Contact Person: Elena Simona Buiga  
Director of RA/QA/ISO  
[simonab@icmedical.com](mailto:simonab@icmedical.com)

Date Prepared: January 25, 2016

### Device:

Trade name: Non-Telescopic PenEvac  
Common Name: Smoke Evacuation Electrosurgical Pencil  
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories  
Classification Regulation: 21 CFR 878.4400  
Device class: 2  
Product code: GEI

### Predicate Device:

Telescoping PenEvac K954088.

### Device Description:

The Non-Telescopic PenEvac is defined as monopolar electrosurgical pencil with smoke evacuation capabilities. The device is designed for general electrosurgical applications including cutting and coagulating and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

The Non-Telescopic PenEvac is intended to be used by trained professionals and will be marketed as a single use device, having different configuration as far as: type of electrode, length of tubing and end connector.

The proposed device is the same as the predicate Telescoping PenEvac. The only modification is a change in the telescopic tip, as the Non-Telescopic PenEvac does not have the telescope capability.

### Intended Use:

The PenEvac<sup>®</sup> is intended to be used as the active Monopolar electrode in an electrosurgery generator system and to facilitate the removal of smoke that is generated during procedure.

### Comparison of Technological Characteristics with the Predicate Device:

This Special 510(k) is a modification to the dimensional specification (change in the telescopic tip) of the Telescoping PenEvac previously cleared by the FDA with the 510(k) number (K954088) as well as addition of different electrode material (PTFE).

No changes were made to the intended use, indication for use, energy type, performance specifications, materials, sterilization method or fundamental scientific technology.

**Performance Characteristics:****Performance Testing-Bench:**

The Non-Telescopic PenEvac was exposed to performance bench testing to ensure conformance with:

IEC 60601-1-Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;

IEC 60601-1-2-Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances –Requirements and tests;

IEC60601-2-2-Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories;

The Non-Telescopic PenEvac meet the acceptance criteria on all applicable clauses of above mention standards.

**Clinical testing:**

There was no clinical testing required to support the medical device, as the indication for use is the same as to the predicate device Telescoping PenEvac. The descriptive information detailed in this submission supports the substantial equivalence of the device.

**Conclusions:**

The difference between the Non-Telescopic PenEvac and the predicate Telescoping PenEvac do not raise any questions regarding its safety and effectiveness.

Testing was performed to required standards to demonstrate that the Non-Telescopic PenEvac has the same function and is the same in terms of design, manufacturing, materials, components, principal of operation, sterilization, biocompatibility, performance characteristics, and intended use as the predicate. The proposed Non-Telescopic PenEvac, as designed, is determined to be as safe and effective as the referenced predicate device, which supports a determination of substantial equivalence.