K113500

DEC - 9 2011

510(k) Summary

(per 21 CFR 807.92(c))

1. Applicant

US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803

Contact Person:
Jerome Canady, M.D.
Tel: 863 667-1609
Fax: 863 667-1917

Date Prepared: October 11, 2011

2. Device Name and Classification

Trade Name(s): Canady Vieira Hybrid Plasma™ Scalpel, AW-422552

Common Name: Electrosurgical, cutting & coagulation & accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories

Classification Regulation: 21 CFR 878.4400
Panel: General, Restorative, and Neurological Devices
Product Code: GEI
Class: II

3. Predicate Devices

The Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent to the following devices:

510(k) Number	Device	Manufacturer
K955020	Telescoping Pen Evac ABC	I.C. Medical, Inc.
K964636	Force Argon II Argon Enhanced	Valley Lab

4. Description of the Device

The Canady Vieira Hybrid Plasma™ Scalpel is an accessory multi-functional electrosurgical handpiece used for open surgical procedures where monopolar radio frequency electrosurgical handpieces (cutting, coagulation) is normally used. The handpiece uses radio frequency (RF)

monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with radio frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation.

The handpiece consists of three major components: Handle, Telescoping Nozzle, and Electrode. The insulated handle encases the radio frequency (RF) current and gas tubing for controlling the flow of argon gas and activation of RF current for the device. RF current is activated by two push buttons yellow (standard CUT mode) and blue (standard COAG mode) which are top of the handle. Argon gas is delivered via the handle by activating a third push button (purple) which is also on top of the handle. The electrode tip has 4 modes of operation and as shown in the below table, this words appear depending on the mode of operation that is necessary.

Table 5-1

Canady Vieira Hybrid Plasma™ Scalpel Mode	Operation being performed
CUT	Cuts Tissue
COAG	Coagulates Tissue
ARGON PLASMA COAG	Coagulates Tissue
CANADY VIEIRA HYBRID PLASMA CUT	Cuts Tissue

Depending on the RF current mode (CUT or COAG), the handpiece can function in the following argon modes: HYBRID PLASMA CUT – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the CUT mode. Hybrid Argon Plasma Cut mode will cut and coagulate the tissue at the same time. ARGON PLASMA COAGULATION – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the COAG mode. Argon Plasma Coagulation will coagulate the tissue. The Canady Vieira Hybrid Plasma™ Scalpel is an accessory that is used with the Argon 2 (CPC2) and Argon 4 (CPC4) generators, previously cleared by FDA. These generators provide a controlled flow of argon to the electrosurgical handpiece during Hybrid Plasma Cutting or Argon Plasma Coagulation modes. The Physician manually sets the flow rate on the Plasma coagulator. The telescoping nozzle can be extended or shortened over the electrode as desired when the surgeon is performing argon procedures.

5. Indications for Use (IFU)

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

6. Summary of Performance Data

Biocompatibility Testing

Biocompatibility testing was performed to validate the patient contacting material used for the Canady Vieira Hybrid Plasma™ Scalpel. These tests were conducted to meet ISO 10993-1 and USP requirements.

Performance Testing – Bench Studies

Testing was completed to ensure that the Canady Vieira Plasma ™ Scalpel meets the requirements of IEC 60601-1-2 and IEC 60601-2-2 and to ensure that it is compatible with the Canady Plasma Argon 2 and Argon 4 Electrosurgical Generators SS-200-E and SS-601-MCa. Bench Testing was also performed to ensure cutting and coagulation using the device, as well as shelf life and sterility testing.

Performance Testing – Clinical Studies

No Clinical studies were performed for the submission of this 510(k).

7. Safety & Effectiveness

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A
Indications for Use	Hybrid Plasma provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Reusable	No	Yes	No	None
Sterilization Method	EO	EO	EO	None
Needle tip length	2.5cm	2.5cm	2.5cm	None
Buttons on scalpel	3 buttons	3 buttons	3 buttons	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

As demonstrated in the above table the Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent to the predicate devices listed in this 510(k) submission. The Canady Vieira Hybrid Plasma ™ Scalpel compared to the predicate devices does not raise issues with regards to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC - 9 2011

U.S. Medical Innovations, LLC
% TÜV SÜD America, Inc.
Mr. Alexander Schapovalov
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K113500
Trade/Device Name: Canady Vieira Hybrid Plasma™ Scalpel
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 22, 2011
Received: November 25, 2011

Dear Mr. Schapovalov:

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 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: Canady Vieira Hybrid Plasma™ Scalpel

Indications for Use:

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K113500

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC - 9 2011

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% TÜV SÜD America, Inc.
Mr. Alexander Schapovalov
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K113500
Trade/Device Name: Canady Vieira Hybrid Plasma™ Scalpel
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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.

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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: Canady Vieira Hybrid Plasma™ Scalpel

Indications for Use:

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K113500

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 25, 2011

US MEDICAL INNOVATIONS LLC
c/o TUV SUD AMERICA INC.
1775 OLD HIGHWAY 8 NW
NEW BRIGHTON, MINNESOTA 55112-1891
ATTN: NORBERT STUIBER

510k Number: K113500

Received: 11/25/2011

Product: CANADY VIEIRA HYBRID PLASMA SC

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

FDA Checklist

Yes	No	N/A	
☒	☐	☐	The FDA cover letter, FDA_F_09.06e.doc
☒	☐	☐	FDA Certification, FDA_F_18.05e.doc
☒	☐	☐	COI Declaration, FDA_F_09.12e.doc
☒	☐	☐	SE Decision Documentation, FDA_F_09.05e.doc Special 510(k): ODE Review Memorandum (if applicable)
☒	☐	☐	SE flowchart, FDA_Flowchart.doc
☐	☐	☒	Any final Technical Reports from reviewers, FDA_Report.doc
☐	☐	☒	Mfr. Response to deficiency letter
☒	☐	☐	Substantive review deficiency letter, FDA_F_09.04e.doc
☒	☐	☐	Substantive review deficiency records, FDA_F_09.05e1.doc
☒	☐	☐	Submission Acceptance Letter, FDA_F_09.09e.doc
☐	☐	☒	Mfr. Response to deficiency letter
☐	☐	☒	Administrative review deficiency letter, FDA_F_09.04e.doc
☐	☐	☒	Checklist for acceptance deficiency, FDA_F_09.03e.doc
☒	☐	☐	Checklist for acceptance decision, FDA_F_09.01e.doc
☒	☐	☐	Checklist for acceptance, FDA_F_09.02e.doc
☒	☐	☐	Acknowledgment Letter, FDA_F_09.10e.doc
☒	☐	☐	Manufacturer's Authorization Letter, FDA_F_09.07e.doc
☑	☐	☐	Original Manufacturer's
☑	☐	☐	Indications for Use inside front cover of submission - section prescription use / OTC completed - concurrence of ODE / OIVD
☒	☐	☐	510(k) Summary inside front cover of submission
☒	☐	☐	Truthful and Accuracy Statement
☒	☐	☐	Signed Quotation and Invoices (TPS copies only)

2011-11-22

TÜV America, Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891
Telephone: 651 631 2487 -- FAX: 651 638 0295

Section 6 – Truthful and Accuracy Statement

Premarket Notification Truthful and Accuracy Statement
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as **manager** for US Medical Innovations, LLC . I believe to the best of my knowledge, that all data and information submitted in the premarket nofification are truthful and accurate and that no material fact has been omitted.

10.05.2011

Jerome Canady, M.D. **10.05.2011**

510(k) Summary

(per 21 CFR 807.92(c))

1. Applicant

US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803

Contact Person:
Jerome Canady, M.D.
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Classification Name: Electrosurgical cutting and coagulation device and accessories

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5. Indications for Use (IFU)

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Biocompatibility Testing

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Performance Testing – Bench Studies

Testing was completed to ensure that the Canady Vieira Plasma ™ Scalpel meets the requirements of IEC 60601-1-2 and IEC 60601-2-2 and to ensure that it is compatible with the Canady Plasma Argon 2 and Argon 4 Electrosurgical Generators SS-200-E and SS-601-MCa. Bench Testing was also performed to ensure cutting and coagulation using the device, as well as shelf life and sterility testing.

Performance Testing – Clinical Studies

No Clinical studies were performed for the submission of this 510(k).

7. Safety & Effectiveness

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A
Indications for Use	The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Reusable	No	Yes	No	None
Sterilization Method	EO	EO	EO	None
Length	3.0m	3.0m	3.0m	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

As demonstrated in the above table the Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent to the predicate devices listed in this 510(k) submission. The Canady Vieira Hybrid Plasma ™ Scalpel compared to the predicate devices does not raise issues with regards to safety and effectiveness.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K113500

Cover Letter FDA

Date: 2011-11-22

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: Traditional 510(k)

B. Name and Address of the Third Party:

TÜV SÜD America, Inc.
1775 Old Highway 8
New Brighton, MN 55112-1891

C. Name and Address of the Manufacturer:

US Medical Innovations, LLC
Mr. Jerome Canady, M.D.
2940 Winter Lake Road
Lakeland, Florida 33803
USA
Contact: Jerome Canady, M.D.
Phone Number: 863 667-1609
FAX Number: 863 667-1917

D. Name of Device:

Trade Name:	Canady Vieira Hybrid Plasma™ Scalpel
Common Name:	Electrosurgical cutting and coagulation device and accessories
FDA Classification Name:	General, Restorative, and Neurological Devices

E. Classification Regulation Number: 21 CFR 878.4400

F. Recommendation: Substantially Equivalent

G. Date TÜV SÜD America Received the 510(k): 2011-10-14

We have also enclosed the following additional material:

H. Manufacturer's Authorization Letter (FDA_F_09.07)

I. Complete 510(k)

J. Review of the 510(k) (FDA_F_09.01, FDA_F_09.02, FDA_F_09.05 and all other correspondence and documents related to the review.)

K. Certification (FDA_F_18.05)

If you should have any questions regarding this submission, please contact the 510(k) reviewer Alexander Schapovalov at +49-89-5008-4309 / fax +49-89-5008-4108 or Norbert Stuiber at +49-89-5008-4144 / fax +49-89-5008-4108 or e-mail: mhs-fa@tuev-sued.de

If you have any formal question regarding this submission, please contact TÜV SÜD America at 001-651-631-2487.

When completed, please fax the substantial equivalence letter to +49-89-5008-4108.
Sincerely,

Norbert Stuiber
Responsible Third Party Official
510(k) TPR Program Manager

FDA Certification (Qualifications,Truthful/Accurate, Review on 510(k), False Information)

TÜV SÜD America

1. I certify that TÜV SÜD America continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by the FDA;

2. In addition, I state that TÜV SÜD America believes that statements made in the review are true and accurate to the best knowledge of TÜV SÜD America;

3. That TÜV SÜD America review is based on the 510(k) that is attached with the review; and

4. TÜV SÜD America understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 33(q).

Norbert Stuiber
Name of Third Party Official

Signature of Third Party Official

Date: 2011-11-22

COI Declaration and Certification
For Specific 510(k) Review and Inspections

TÜV SÜD America

COI Declaration and Certification
for

Manufacturer: **US Medical Innovations, LLC**

Device: **"Canady Vieira Hybrid Plasma™ Scalpel"**

Initials

AS I have read and understand TÜV's COI/Confidentiality Procedure (FDA_P_18.02), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

AS I have not been employed within the last two years by the firm who submitted the 510(k) for evaluation or requested a quality system evaluation.

AS I did not charge fees contingent or based upon the recommendation for initial classification (SE decision) or outcome of an inspection.

AS I have not performed testing in connection with this specific device 510(k).

AS I understand that the Accredited Persons (AP) program requires that the AP or any of its personnel involved in 510(k) reviews or QSR inspections, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.

AS I do not participate in the design, manufacture or distribution of any medical device.

AS I do not provide consultative services to any device manufacturer or distributor regarding specific device 510(k)'s or participate in the preparation of 510(k)s or quality system consultation.

Signed: ASchapovalov

Printed Name: Alexander Schapovalov

Date: 2011-11-18

Please return signed original to 510(k)/QSR Program Manager

Third Party "Substantial Equivalence" (SE) Decision Making Documentation

- Primary Third Party Reviewer:

Signature — Date: 2011-11-18

Alexander Schapovalov
Print Name

- Responsible Third Party Official:

Signature — Date: 2011-11-22

Norbert Stuiber
Print Name and Title
TÜV SÜD PRODUCT SERVICE

Submitter's name and address:

US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803
USA

Contact person and telephone number:
Mr. Jerome Canady, M.D.
Tel: 863 667-1609
Fax: 863 667-1917

Device Name: Canady Vieira Hybrid Plasma™ Scalpel

Table of Contents

I. Purpose and Submission Summary:

The 510(k) sponsor would like to introduce "Canady Vieira Hybrid Plasma™ Scalpel" into interstate commerce.

The original submission was received on 2011-10-14.

Review strategy:

- Review of the submitted documentation against the "Checklist for Acceptance Decision", the "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s"

- Review of the submitted documentation against Sterility Review Guidance K90-1

- Review of the submitted documentation against requirements from applicable standards:

- IEC 60601-1:1998 Medical electrical equipment. General Requirements for safety of high frequency surgical equipment.

- IEC 60601-1-6:2006 Medical electrical equipment general requirements for basic safety and essential performance- Collateral standard: Usability.

- IEC 60601-2-2: 2006 Medical electrical equipment. General Requirements for the safety of high frequency surgical equipment.

- ANSI/AAMI/ISO 10993-1: 2003 Biological evaluation of medical devices. Evaluation and testing.
- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products Ethylene oxide.
- AAMI ST72:2002/(R)2010 Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing. (Sterility)
- ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. (Sterility)

- Comparison of the new device with predicate devices considering construction, dimensions, performance, material and labeling.

I recommend that the new device be found Substantially Equivalent to the cited predicate devices and considered complete.

II. Administrative Requirements

	Page	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or ~~OTC~~)	4-1	X		
Truthful and Accuracy Statement	6-1	X		
510(k) Summary or 510(k) Statement	5-1	X		
Standards Form FDA-3654	9-1	X		
Form FDA 3674 –n/a for Third Party Review				X

III. Device Description

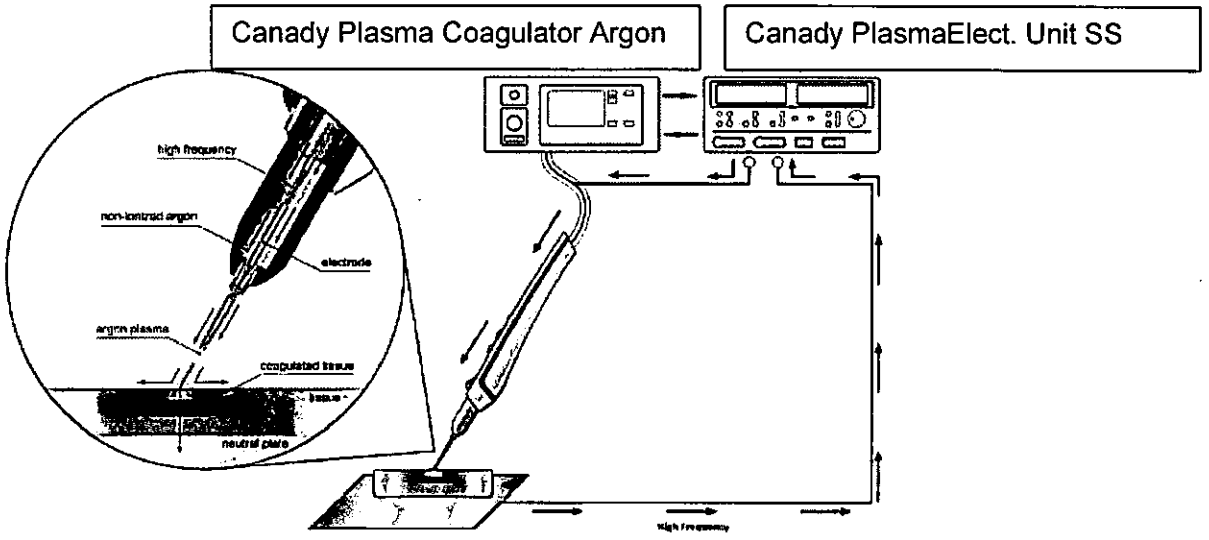
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	

Third Party "Substantial Equivalence" (SE) Decision Making Documentation

Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

The new device **Canady Vieira Hybrid Plasma™ Scalpel** is an accessory multi-functional electrosurgical handpiece used for open surgery and is intended to be only used with 510 (k) cleared Canady PlasmaTM Electrosurgical System SS-200E/Argon 2 or SS-601MCa/Argon 4 (K100669, cleared on 2011-06-04). The generators Argon 2 and Argon 4 provide a controlled flow of argon to the electrosurgical handpiece during Canady Vieira Hybrid Plasma Cutting or Argon Plasma Coagulation modes.

The new device uses radio frequency (RF) monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with radio frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation.



The handpiece consists of three major components: Handle, Telescoping Nozzle, and Electrode. The insulated handle encases the radio frequency (RF) current and gas tubing for controlling the flow of argon gas and activation of RF current for the device. RF current is activated by two push buttons yellow (standard CUT mode) and blue (standard COAG mode). Argon gas is delivered via the handle by activating a third push purple button.

The electrode tip has four high frequency modes of operation (Cut, Coagulation, Argon Plasma Coagulation and Canady Vieira Hybrid Plasma Cut).

IV. Indications for Use

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

The indication for use is identical to the one of the predicate device.

V. Predicate Device Comparison

The **"Canady Vieira Hybrid Plasma™ Scalpel"** is substantially equivalent to the legally marketed predicate devices:

- "Telescoping PenEvac ABC" which was cleared to market under 510 (k) K955020
- "Force Argon II Enhanced Electrosurgical System", which was cleared to market under 510 (k) K964636.

Third Party "Substantial Equivalence" (SE) Decision Making Documentation

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A
Indications for Use	Hybrid Plasma provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Sterilization Method	EO	EO	EO	None
Needle tip length	2.5cm	2.5cm	2.5cm	None
Buttons on scalpel	3 buttons	3 buttons	3 buttons	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

The Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent in design, materials, function and intended use to the following predicate devices Telescoping PenEvac ABC and Force Argon II Enhanced Electrosurgical System.

The new device's mode of action is cut and gas coagulation as it is for all predicate devices. Each predicate device is disposable, sells sterile and used for the monopolar thermal coagulation like the new device and have needle tip length of 2.5 cm.
New and predicate devices have three buttons for cut, coagulation modes and for the delivery of argon gas.
The Indications for Use of the new device is equivalent to the Indications for Use of the Predicate devices.
The sterilization method used by the new device Canady Vieira Hybrid Plasma™ Scalpel is Ethylene oxide and is the same compared to all predicate devices. The manufacturer validated the sterilization process according ISO 11135-1 and provided Standard Data Report (section 9) of the submission.
The comparison of the Gas flow rate between new and predicate devices shows that gas flow rate of the new device (0.1-10.0 l/min) is below as gas flow rate for both predicate devices (0.5-12.0 l/min).

According to the manufacturer's recommendation typically gas flow rate in "argon plasma coagulation" mode is 2 to 5 liters/minute and in "hybrid plasma cut" 2 to 7 liters/minute. (Section 13, appendix 13g)

To prove safety and effectiveness the new device was successfully tested according to IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2. Bench tests were also made to show that the new device Canady Vieira Hybrid Plasma™ Scalpel performs as intended.

VI. Labeling

The submitted labelling information is comprised of the following documents:

- new device:
  1. User Manual of Canady Plasma Coagulator Argon 2
  2. User Manual of Canady Plasma Coagulator Argon 4
  3. Canady Vieira Hybrid Plasma™ Scalpel Safety Sheet
  4. Box Label of Canady Vieira Hybrid Plasma™ Scalpel
  5. Inner Label of the Canady Vieira Hybrid Plasma™ Scalpel
  6. Sales brochure of Canady Vieira Hybrid Plasma™ Scalpel
- predicate devices:
  1. Sales brochure "Force Argon II Enhanced Electrosurgical System"

The indications for use are described in the operation manuals for canady plasma coagulator Argon 2 on the page 5, canady plasma coagulator Argon 4 on the page 5 and in the Canady Vieira Hybrid Plasma Scalpel Safety Sheet (appendix 13C). They are consistent with the indications for use form information. The labelling contains the prescription use statement according to 21 CFR 801.109.

VII. Sterilization/Shelf Life/Reuse

The applicant claimed sterilisation testing and shelf life testing are the same as for accessories of the device manufactured by the applicant and cleared on 6th of April 2011 (K100669), section 14.

Additional the applicant provided sterilization and shelf life data for the new device. The sterile labelled Canady Vieira Hybrid Plasma™ Scalpel is sterilized using a traditional sterilization method with ethylene oxide. The sterilization process is validated in accordance to ISO 11135-1.

The applicant provided information according to the updated 510 (k) Sterility Review Guidance K90-1, after my request of additional information on October 24, 2011. The document is attached to the original submission.

The rate of residual ethylene oxide and ethylene chlorhydrin (according to ISO 10993-7) is lower to fixed limits:

-REO rate <0.5 mg/article
-RCE rate<0.5 mg/article

A SAL of 10^{-6} is achieved according to the section 14 (appendix 14F) in the original submission .

Canady Vieira Hybrid Plasma™ Scalpel is labeled as "pyrogen free". It is tested for bacterial endotoxin. The method used to make that decision is based on the Limulus Amebocyte Lysate (LAL) test.
LAL testing. This study was conducted according to the requirements of the USP 32/NF27-2009

- Sample washed with 10.0ml of apyrogenic sterile water
- Incubation of the LAL sample for duration: 60 ± 2 minutes
- Temperature: 37±1°C
- Lysate Sensitiveness: 0.125 EU/ml

Results: Under the conditions of this study, corresponding concentration below 0.5 EU/ml.
For more detailed information please see test report 310612/004/004 in the appendix 15D, section 15 of the original submission.

The above mentioned medical device was also tested to demonstrate microbial inactivation. Twelve samples of finished packaged devices were tested using ethylene oxide 90%/CO2 10%. The chamber's temperature was 50 o C/+/- 10 o at a pressure of -0, 30 Kgf/cm2 +/- 0,1 at a relative humidity of 55 +/- 25%. The exposure time was 120 minutes. After the sterilisation all indicators showed no evidence of microbial growth.

Sterility validation test provided in the assay report Nr. 310612/003/004 according to USP 32/NF 27-2009 showed also no evidence of microbial growth on both samples after 14 days of incubation.
A validation protocol and sterility reports are part of the original submission (appendix 14A, 14B and 14C).

Evaluation of packaging stability under accelerated storage condition (after 32, 64 and 96 days of storage at 60°C equivalent to periods of real time storage 1, 2 and 3 years respectively according to ASTM F1980, for each period will be evaluated five packages) has been performed. Shelf-life testing on simulated aged sterile packaging has been carried out and showing that the tensile seal strength and sterility for packaging of the medical devices is assured for the expiration date defined for the products (3 years). See test report CETEA A035-2-I/11-Final in the original submission in the section14, appendix 14E.

The Standards Data Report FORM 3654 for standard ISO 11135-1, 2007 is provided by the applicant in the original submission

VIII. Biocompatibility

The following components of the new device Canady Vieira Hybrid Plasma™ Scalpel have a contact with the patient:

- Probe Tip made of ceramic
- Electrode, made of tungsten

Both components made from the same materials as components of the predicate devices "Telescoping PenEvac ABC" (K955020) and Force Argon II Enhanced Electrosurgical System (K964636)

General Information about Biocompatibility has been provided in the Section 15. "Biocompatibility" of the submitted original documentation.

The new device Canady Vieira Hybrid Plasma™ Scalpel is medical device classified in the device category "external communicating devices" in contact with tissue / bone with a limited duration (< 24 h) as per ISO 10993-1.

In accordance with ISO 10993-1, the following required biological evaluation tests have been selected:

- *Cytotoxicity*. This study was conducted according to the requirements of the ISO 10993 standard: Biological Evaluation of Medical Device, Part 5 (1999):

  An extract of the test articles was prepared as follows:

  - Cell lineages: NCTC Clone 929, mouse conjunctive tissue cells (ATCC CCL1)
  - Extraction transmitters: saline solution or cottonseed oil
  - Temperature: 37°C
  - Duration: 24 hours

  Positive and negative controls were performed.

  Result: Under the conditions of this study, the extract of the test articles showed no toxic effect to the cell lineage NCTC Clone 929 (ATCC CCL-1). The negative and positive controls performed as anticipated.
  For more detailed information please see test report 304423/009/009 in the appendix 15B of the original submission

- *Irritation / Intracutaneous*. This study was conducted according to the requirements of the USP 32/NF27-2009

- The extracts were prepared as follows:
  Extraction vehicle: 0.1 g of sample to 1.0 ml of sterile saline solution heated at 70°C during 24 hours.
- Two adult New Zealand albino mouse
- The sites were examinated 4, 24, 48 and 72 hours after injection, for gross evidence of tissue reaction, such as erythema and edema.

- Results: Under the conditions of this study no macroscopic abnormalities in both animals were observed.

- *Sensitization*. This study was conducted according to the requirements of the ISO 10993 standard – Part 10

Skin Sensitization Study used 20 albino healthy guinea pigs. The animals were divided in three groups (test group- 10 animals, control group 1 with 5 animals, control group 2 with 5 animals).
As reference substance was used 0.9% NaCl,
Canady Vieira Hybrid Plasma™ Scalpel was extracted in an oven at 70°C for 24 hours at 2 units of the sample to 450 ml of saline.

Induction phase:
All animals in the test group received an intra dermal injection of 0.1 ml Freund's Complete Adjuvant.
Canady Vieira Hybrid Plasma™ Scalpel was applied topically to the test group and to control 2 group. 0.9% NaCl was topically applied to Control group 1. The treatment was suspended from the 24th day to the 35th day.
Challenge Phase:

Canady Vieira Hybrid Plasma™ Scalpel was applied topically to the test group and to control 1 group for 48 hours. Control group 2 topically received 0.5 ml of 0.9% NaCl. Each animal was evaluated separately after 1, 6 24 and 48 hours.

Results: The topical application of the test article, according to the ISO 10993-10 standard, did not induce delayed sensitization in the guinea pig (grade 0) for test group, control group 1 and control group 2.

- *Acute Systemic Toxicity*. This study was conducted according to the requirements of the ISO 10993 standard: Biological Evaluation of Medical Device, Part 11 (2006): Tests for Systemic Toxicity.

  The extracts were prepared as follows:
  - Extraction vehicle: NaCl solution and cottonseed oil
  - Duration: 24 hours
  - Temperature: 70°C

  A single dose of each extract was injected into five mice per extract, by either the intravenous route for the NaCl extract or the intraperitoneal route for the sesame oil extract, at the dose of 25 mL/kg. Similarly, five mice were injected with each corresponding extraction vehicle. The animals were observed 24, 48 and 72 hours after systemic injection.

Result: Under the conditions of this study, there was no evidence of significant systemic toxicity or mortality after test article extracts injection. Each test article extract met the requirements of the ISO 10993-11 standard.

IX. Software

not applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The new device Canady Vieira Hybrid Plasma™ Scalpel has been designed to comply with the standards:

- IEC 60601-1: 1988
- IEC 60601-2-2: 2006
- IEC 60601-1-2: 2001

No safety or effectiveness issues have been raised during electrical tests.

Standard data reports (Section 9.1) are provided in the submitted original documentation.

The provided data found to be acceptable.

XI. Performance Testing – Bench

(b)(4)

(b)(4)

A test report, dated 2011-09-22, including the test description and results is provided in the original submission appendix 18A.

(b)(4)

(b)(4)

The results show that measured power with both devices combinations is in the range with specified power.

XII. Performance Testing – Animal

n/a

XIII. Performance Testing – Clinical

n/a

XIV. Substantial Equivalence Discussion

Third Party "Substantial Equivalence" (SE) Decision Making Documentation

	YES	NO	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See the Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:
   The descriptive characteristics are not fully sufficient to demonstrate substantial equivalence. The new device requires in addition performance data to demonstrate safety & effectiveness (e.g. biocompatibility, electrical safety, bench performance tests).

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods cannot be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The provided performance data for the Canady Vieira Hybrid Plasma™ Scalpel demonstrates that the new device is as safe and effective as the predicate devices. Performance tests according recognized consensus standards were provided for the relevant criteria. The data demonstrates substantial equivalence of the new device with the predicate comparison devices.

XV. Deficiencies

(b)(4)

(b)(4)

Third Party "Substantial Equivalence" (SE) Decision Making Documentation

(b)(4)

(b)(4)

(b)(4)

(b)(4)

XVI. Contact History

The manufacturer's original submission was received on October 14, 2011. The submission was reviewed against the FDA guidelines and standards as listed in section I of this decision making document.
On October 21 and October 27, 2011 the deficiencies identified in the course of the review have been communicated to the applicant. The response to the deficiencies has been received on November 04, 2011

XVII. Recommendation

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI

The information provided within the submission contains adequate information according to the requirements. The documentation demonstrates that the new device is as safe and effective as the legally marketed comparison devices.
I recommend that this application be found Substantially Equivalent to the cited predicate devices and considered complete.

requirements for the safety of high frequency surgical equipment and was conducted by an outside laboratory, see **Appendices 17** for information.

Shelf Life and Sterility Testing

US Medical Innovations also performed accelerated aging studies per ASTM F1980-07, the device has a shelf life of 3 years and has an expiration date listed on the label based on this shelf life data. Sterility test performed met the requirements of ISO 11135 USP 85, and ANSI/AAMI ST72. All shelf life and sterility tests passed. All recognized consensus standards that were used for these tests are listed in the applicable US FDA Form 3654 and on the CDRH Cover Sheet in **Section 2** of this 510(k) application. A summary is provided in **Section 14** with regards to Sterility and Shelf life the actually reports are listed in **Appendices 14**.

Performance Testing- Animal

(b)(4)

(b)(4)

Performance Testing – Clinical

No Clinical studies were performed for the submission of this 510(k).

Risk Analysis

A comprehensive Risk Analysis (RA) was conducted by the manufacturer (US Medical Innovations, LLC) to identify the inherent risks associated with the Viberect. Reflexonic identified all risks and then ranked them as to their severity and likelihood of occurrence; the type of harm they could cause; and how the risks could be mitigated and/or dealt with if they occurred (e.g., WARNING statement in the User's Guide.) Based on this analysis it was concluded that the benefits of the Canady Vieira Plasma™ Scalpel clearly outweighed the potential risks.

12.4 Substantial Equivalence Table

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A

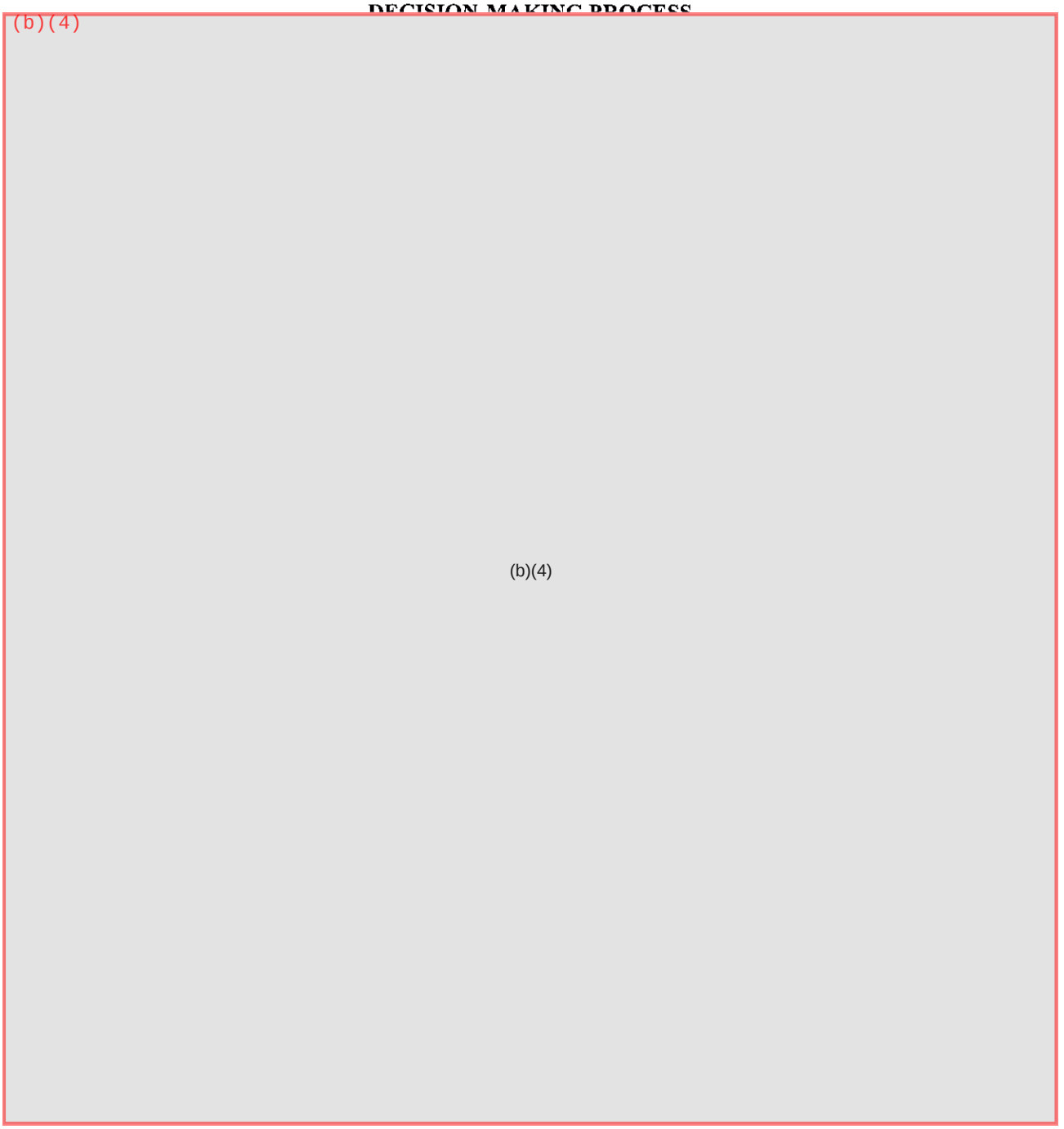
Indications for Use	Hybrid Plasma provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Reusable	No	Yes	No	None
Sterilization Method	EO	EO	EO	None
Needle tip length	2.5cm	2.5cm	2.5cm	None
Buttons on scalpel	3 buttons	3 buttons	3 buttons	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

12.5 Substantial Equivalence Discussion

The Canady Vieira Hybrid Plasma™ Scalpel is classified as a Class II device under FDA Product Code GEI under 21 CFR 878.4400. This device has no significant difference in intended use, technology, materials, performance, and sterilization method compared to the predicate devices. As mentioned in the above section 10.4 all devices use the same materials and are monopolar devices. (b)(4) (b)(4) different between the Canady Vieria Hybrid Plasma and the predicate devic(b)(4) (b)(4) (b)(4) (b)(4) The indications for use is also similar amongst all three devices. The Canady Vieira Plasma™ Scalpel and the predicate devices do not raise issues of safety and effectiveness.

510(k) "SUBSTANTIAL EQUIVALENCE"
DECISION-MAKING PROCESS

(b)(4)



2011-11-18

* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

510(k) SUMMARY REQUIREMENTS CHECKLIST 21 CFR 807.92				
All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared	X		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	X		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	X		
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	X		
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.	X		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.	X		
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence	X		
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)			X
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.	X		

14. Sterilization & Shelf Life

14.1 Sterilization

The Canady Vieira Hybrid Plasma ™ Scalpel is sterilized using Ethylene Oxide (EtO). The finished device is (b)(4) (b)(4) (b)(4) (b)(4) and the final device is sterilized via Ethylene Oxide (EtO).

As part of this 510(k) submission (b)(4) (b)(4) devices, The Canady Vieira Hybrid Plasma ™ Scalpel, were tested to meet ISO 11135-1:2007-"Serilization of Health Care Products-Ethylene Oxide-Part 1" as part of the sterilization validation. The method that was used for sterilizing agent used was ethylene oxide 90%/CO^2 10%. The chamber's temperature was 50 ° C/+/- 10 ° at a pressure of -0, 30 Kgf/cm^2 +/- 0,1 at a relative humidity of 55 +/- 25%. The exposure time was 120 minutes. According to the report reference number 8618 all chemical indicators showed no microbial growth, the results were negative. The sterilization protocol and report is located in **Appendix 14A and 14B respectively.** A Sterility Assay report (NR.310612/003/004) was completed in accordance with USP 32/NF 27-2009 which is located in **Appendix 14C**. The testing that was done for the Canady Vieira Hybrid Plasma™ Scalpel is the same testing that was completed on the Canady Probes in K100669 that received clearance in April 2011.

14.2 Shelf Life

The Canady Vieira Hybrid Plasma ™ Scalpel U.S. Medical Innovations completed an accelerated aging on the product per ASTM F1980-07 "Accelerated Aging of Sterile barrier Systems for Medical Devices". The the device has a shelf life of 3 years and has an expiration date listed on the label based on this shelf life data. The test that was performed was at a temperature of 60 ° C for 96 days to simulate a time period of 3 years. 5 finished device packages were tested for each time interval for seal integrity and tensile seal strength based on test report CETEA A035-2-I/11-Final, this report is located in **Appendix 14D and 14E.** The testing that was done for the Canady Vieira Hybrid Plasma™ Scalpel is the same testing that was completed on the Canady Probes in K100669 that received clearance in April 2011.

Pages 46 through 49 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Test Results

17. Electromagnetic Compatibility and Electrical Safety

The Canady Vieira Hybrid Plasma ™ Scalpel complies with IEC 60601-1-2 Int. 1 Third Edition/I-SH 01:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Interpretation as well as with IEC 60601-1 Standard, Electromedical equipment – Part 1 – General requirements for safety, NBR IEC 60601 – 2 – 2 Electromedical equipment –Part 2 – 2: Particular requirements for the safety of high frequency surgical equipment and was conducted by an outside laboratory WEM Equipamentos Eletronicos LTDA. Both test passed the requirements according to Test Report Numbers AW002/2011 and AW003/2011 which is located in **Appendices 17a and 17b**.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requir.for Safety - Collateral standard: Electrom.Compatibility

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-34	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requir.for Safety - Collateral standard: Electrom.Compatibility

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5-34	IEC 60601-1-2	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
None

DESCRIPTION
Medical Electrical Equipment - Part 1-2: General Requir.for Safety - Collateral standard: Electromagnetic Compatibility - Requir. and Tests. Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)). (General)

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

15. Biocompatibility

The patient contacting components are the probe tip and the electrode. The probe tip is made of ceramic and the electrode is made of tungsten, these are the exact same materials used in the predicate devices. For more detailed information on the contacting materials please refer to **Section 11 Device Description.**
According to ISO 10993-1 this device is considered an external communicating device and has indirect contact with the blood path, the contact is less than 24 hours. All test that are required by ISO 10993-1 were performed including Blood Compatibility Assay, In-Vitro Cytotoxicity, Systemic Acute Toxicity, LAL Endotoxin, and Intracutaneous Biological testing. The detailed reports for each test are located in **Appendices 15**.

15.1 10993-4 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
The test evaluated the hemolytic properties of materials that are intended to be in contact with blood, was performed to validate the time to clot was observed. The results of this test showed that the results were satisfactory and did not vary the clotting time by more than 10%. The detailed report **NR304423/008/009** is located in **Appendix 15a**.

15.2 10993-5 _Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

The test evaluated the cytotoxicity potential and was conducted in conjunctive tissue cells of mice. The results of this test showed that the device samples that were provided did not present toxic effect to the cells. The detailed report **NR304423/009/009** is located in **Appendix 15b**.

15.3 USP 32/NF27-2009 Intracutaneous Biological Reactivity

The test evaluated macroscopic abnormalities in New Zealand albino mice potential. The results of this test showed that the device samples that were provided did not present abnormalities. The LAL testing was also conducted per this USP, and the concentration was below 0.5 EU/mL, per FDA medical device specifications. The detailed report **NR304423/011/011 NR310612/004/004** is located in **Appendix 15c and Appendix 15d,** respectively.

15.4 ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
The test showed that the device samples that were provided did not present abnormalities in the guinea pigs. The detailed report **SDM 304423/012/012** is located in **Appendix 15f.**

15.5 10993-11 _Biological evaluation of medical devices -- Part 11: Tests for systemic acute toxicity

The test evaluated the systemic response during a short "in-vitro" observation period in a Swiss albino mouse. The results of this test showed that the device samples that were provided did not show a difference from the control group. The detailed report **NR304423/010/011** is located in **Appendix 15e**.

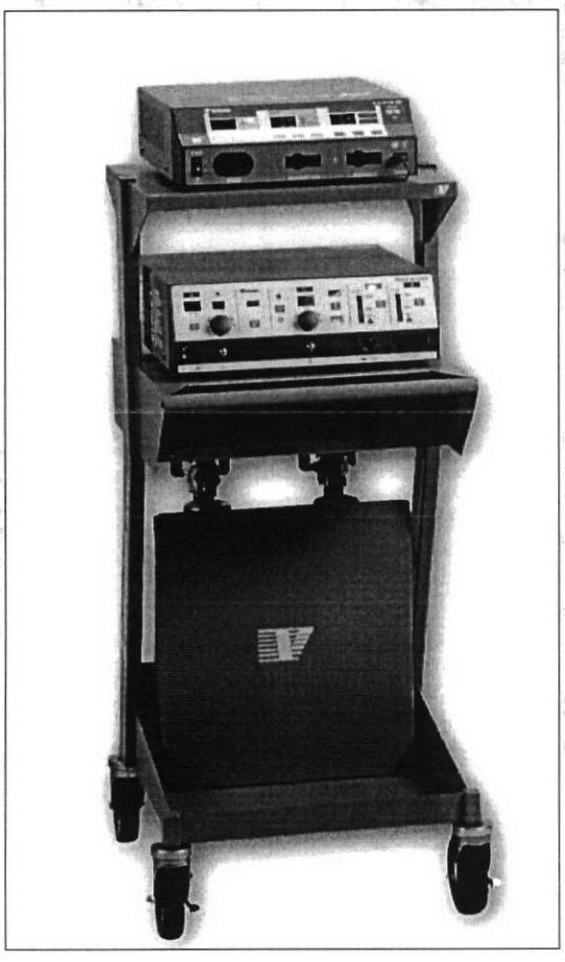
15.6 Summary

Biocompatibility testing was performed to validate the patient contacting material used for the Canady Vieira Hybrid Plasma™ Scalpel device. These tests were conducted in accordance with USP 32 or ISO 10993 and showed that the patient contacting material was nontoxic and did not cause an adverse reaction .

Pages 57 through 61 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Test Results

Force Argon™ II System

Improved precision and control in electrosurgery



Now the benefits of precise, controlled argon-enhanced electrosurgery are available in a compact, easy to operate unit – the Force Argon™ II System from Valleylab.

PRECISION

Argon-enhanced coagulation offers precise energy delivery for efficient, noncontact coagulation over large surface areas. Argon-enhanced coagulation produces rapid hemostasis with a thinner, more flexible eschar, reduced rebleeding, and less tissue damage.

VISIBILITY

Argon-shrouded cut facilitates cutting with less smoke and enhanced visibility.

PATIENT SAFETY

Gas flow control enhances patient safety. The low flow rate, designed to help prevent overpressurization in laparoscopic procedures, is automatically invoked at system start up. Standard flow rate may be selected for open procedures.

VERSATILITY

Multifunction handset provides delivery of standard or argon-enhanced electrosurgery.

FLEXIBILITY

The Force Argon™ II system design reduces space requirements and offers optimal surgical flexibility. The compact unit is compatible with a full range of Valleylab™ electrosurgical generators and argon accessories.

Valleylab™

UNIVERSAL MOUNTING SYSTEM

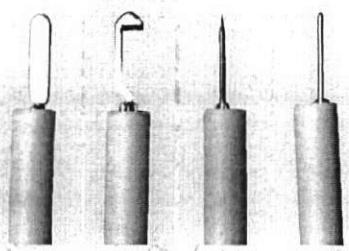
designed to accomodate several pieces of equipment efficiently and conveniently.

COMPATIBILITY WITH ARGONPLUS™ HANDSET

allows the Force Argon™ II System to be used with the Valleylab™ four-function handset and a variety of electrodes designed for open and laparoscopic surgery.

Blade electrode Sharp needle

Flat L electrode Blunt needle



Force Argon™ II System

Technical Specifications

Weight and Dimensions

Height:	14.0 cm (5.6 in.)
Width:	41.0 cm (17.8 in.)
Length:	45.0 cm (16.0 in.)
Weight:	12 kg (24 lbs)

Gas Flow Range

Standard Mode:
0.5-12 standard liters/minute ± 15% of full scale
Low Flow Mode:
0.5-4 standard liters/minute ± 15% of full scale

Gas Filtration System

0.1 micron internal filter
1.2 micron external filter

Overpressure Monitoring

Audio and visual alarm, user selectable setpoint
Active in low flow mode

Input Power Source

Operating Range:	120-240 VAC
Line Frequency:	50-60 Hz
Current:	< 0.5 Amperes

Audio Volume

The alarm tones are set at a minimum 65 dB at 1 meter and are adjustable.

Operating Perameters

Temperature Range:	50° to 104° F (10° to 40° C)
Humidity Range:	15% to 85% noncondensing

Storage and Shipping

Temperature Range:	-40° to 158° F (-4° to 70° C)
Humidity Range:	25% to 85% noncondensing

Approvals

CE 0086 IEC601-1

Order Information

CATALOG NUMBER	DESCRIPTION	ORDER QUANTITY
Force Argon™ II	Portable argon gas delivery system. It includes overpressure monitor and one gas regulator. Electrosurgical generator and argon gas tanks sold separately.	1 each
Force FX™	Microcontroller-based isolated electrosurgical generator, designed for all general surgical procedures. Unit includes the Valleylab™ autoranging REM™ and Instant Response™systems.	1 each
E2520H	Single use ArgonPlus™ handset for delivery of standard or argon-enhanced electrosurgery. Includes single use holster and retractable 2.5 cm (1 in.) blade electrode. Requires E0502-12 adapter.	10/case
E0502-1	Adapter for ArgonPlus™ Handset	1 each
GR200A-20	Argon gas regulator for second argon tank hook-up.	1 each
GT100	Argon tank hook-up, G-size, 42 cubic feet	1 each
UC8009	Base Cart	1 each
UC8010	Optional Overshelf	1 each
UC8011	Optional Cord Management Kit (2 brackets)	1 each
UC8015	Optional Argon Gas Tank Kit	1 each
Sterile, Single Use ArgonPlus™ Electrodes		
E2530-3	7.6 cm (3 in.) flexible coagulation only electrode	10/case
E2530-6	15 cm (6 in.) flexible coagulation only electrode	10/case
E2530-28	28 cm (11 in.) flexible coagulation only electrode	10/case
E2580-28	28 cm (11 in.), 5 mm laparoscopic extender with blade electrode	10/case
E2581-28	28 cm (11 in.), 5 mm laparoscopic extender with modified flat L electrode	10/case
E2582-28	28 cm (11 in.), 5 mm laparoscopic extender with tungsten sharp needle electrode	10/case
E2583-28	28 cm (11 in.), 5 mm laparoscopic extender with tungsten blunt needle electrode	10/case
E2532	2.5 cm (1 in.) tungsten sharp needle electrode	50/case
E2533	2.5 cm (1 in.) tungsten blunt needle electrode	50/case

Valleylab
a division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301-3299 USA
Valleylab direct: 800 255 8522
To order products: 800 722 8722

tyco Healthcare

Valleylab

 Printed in USA 1003345 reorder no: LARGONII 8/06

Letter of Submission Deficiencies

Date: October 27, 2011

US Medical Innovations, LLC
Mr. Jerome Canady, M.D.
2940 Winter Lake Road
Lakeland, Florida 33803
USA

RE: 510(k) "Canady Vieira Hybrid Plasma™ Scalpel"

Dear Mr. Jerome Canady:

Enclosed is supporting documentation (FDA_F_09.03) detailing deficiencies that we found upon review of your 510(k) submission for "Canady Vieira Hybrid Plasma™ Scalpel".

Upon receipt of your responses, TÜV SÜD America Inc. will restart the review process.

Sincerely,

Alexander Schapovalov
Foreign Affairs
TÜV SÜD America, Inc.
Phone: +49 89 5008-4309
Fax: +49 89 5008-4108
E-mail: alexander.schapovalov@tuev-sued.de

Record of Deficiencies

TÜV SÜD America

(b)(4)

(b)(4)

Letter of Submission Deficiencies

Date: October 21, 2011

US Medical Innovations, LLC
Mr. Jerome Canady, M.D.
2940 Winter Lake Road
Lakeland, Florida 33803
USA

RE: 510(k) "Canady Vieira Hybrid Plasma™ Scalpel"

Dear Mr. Jerome Canady:

Enclosed is supporting documentation (FDA_F_09.03) detailing deficiencies that we found upon review of your 510(k) submission for "Canady Vieira Hybrid Plasma™ Scalpel".

Upon receipt of your responses, TÜV SÜD America Inc. will restart the review process.

Sincerely,

Alexander Schapovalov
Foreign Affairs
TÜV SÜD America, Inc.
Phone: +49 89 5008-4309
Fax: +49 89 5008-4108
E-mail: alexander.schapovalov@tuev-sued.de

Record of Deficiencies

TÜV SÜD America

(b)(4)

(b)(4)

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891
(651) 631-2487

Letter of Submission Acceptance

Date: October 20, 2011

US Medical Innovations, LLC
Mr. Jerome Canady, M.D.
2940 Winter Lake Road
Lakeland, Florida 33803
USA

RE: 510(k) "Canady Vieira Hybrid Plasma™ Scalpel"

Dear Mr. Jerome Canady:

TÜV SÜD Product Service has completed our checklist of acceptance for your 510(k) submission and has found no deficiencies. The substantive, (i.e., technical) review of the submission will now begin.

Sincerely,

Alexander Schapovalov
510(k) Third Party Reviewer

Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Part I)

Part I - Acceptance / Non-Acceptance

1. Third Party:

Name: TÜV SÜD America Inc.
Address: 1775 Old Highway 8 NW
New Brighton, MN 55112-1891
Contact: Alexander Schapovalov
Telephone No: +49895008 4103 Fax No: +49895008 4108

2. For Foreign Third Parties, Specify A Domestic Correspondent:

Name:
Address:
Contact:
Telephone No: Fax No:

3. 510(k) Owner (could be manufacturer, specifications developer, or other person preparing the 510(k)):

Name: US Medical Innovations, LLC
Address: 2940 Winter Lake Road, Lakeland, Florida 33803, USA
Contact: Jerome Canady
Telephone No: 863 667-1609 Fax No: 863 667-1917

STOP!
Before completing items 4 through 9 below, complete part II checklist questions 1 through 27 beginning on page 1 of FDA_F_09.02.

Third Party Premarket Notification (510(k))
Checklist for Acceptance Decision (Part I)

TÜV SÜD America

4. Device Name:
Trade or Proprietary: Canady Vieira Hybrid Plasma™ Scalpel

Classification Name: Electrosurgical cutting and coagulation device and accessories

5. CFR Classification Citation: 21 CFR 878.4400 (see 21 CFR 862 through 892)

6. Classification Panel: General, Restorative, and Neurological Devices

7. Based on my completion of pages 1 and 2 of FDA-F_09.01 and pages 1 through 5 of FDA_F_09.02, I recommend that this 510(k):

- ☒ Be accepted for substantive review and I have notified the 510(k) owner using FDA_F_09.09.
- ☐ Not be accepted for substantive review and I have listed the deficiencies on FDA_F_09.03

8. Primary Third Party Reviewer:

Signature — 2011-10-20 Date

Alexander Schapovalov
Print Name

9. Responsible Third Party Official

Signature — 2011-10-20 Date

Norbert Stuiber
Print Name

510(k) TPR Project Manager
Print Title

Third Party Premarket Notification Checklist for Acceptance (Part II)

TÜV SÜD America

Part II - Checklist	YES	NO	Instructions
1 a). Is the device one that FDA has determined as being acceptable for third party review?	✓		If NO, telephone DSMA for instructions. --STOP REVIEW--
1 b). Have you confirmed that the manufacturer has not engaged in forum shopping?	✓		If NO, telephone DSMA for instructions. --STOP REVIEW--
2. Is the device trade or proprietary name included?	✓		If NO, note deficiency on FDA_F_09.03.
3. Is the device common or usual name included?	✓		If NO, note deficiency on FDA_F_09.03.
4. Is the device classification name, class of the device, and regulation number (21 CFR § 78.4400) included?	✓		If NO, note deficiency on FDA_F_09.03.
5. Is the classification panel included?	✓		If NO, note deficiency on FDA_F_09.03.
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	✓		If NO, note deficiency on FDA_F_09.03.
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	✓		If NO, note deficiency on FDA_F_09.03.

Third Party Premarket Notification Checklist for Acceptance (Part II)

TÜV SÜD America

13. (con't) Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a pre-amendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA hasdetermined is SE to another marketed device (21 CFR 807.92(a)3). IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE. If it is not, the review must STOP. Telephone DSMA for assistance.			
14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?	✓		If NO, note deficiency on FDA_F_09.03.
15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)	✓		If NO, note deficiency on FDA_F_09.03.
16. Does the submission contain the Truthful and Accurate Statement (per 21 CFR 807.87(j))?	✓		If YES, indicate page number 6-1. If NO, note deficiency on FDA_F_09.03.

Third Party Premarket Notification Checklist for Acceptance (Part II)

TÜV SÜD America

17. Does the submission contain the standards form (Form 3654) for any used standard?	✓		If NO, note deficiency on FDA_F_09.03.
18. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	✓		If NO, note deficiency on FDA_F_09.03.
19. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and fax number?	✓		If NO, note deficiency on FDA_F_09.03.
20. Does the submission contain a table of contents with pagination?	✓		If NO, note deficiency on FDA_F_09.03.
21. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?	✓		If deficient, note on FDA_F_09.03.
22. Does the submission contain a comparison table of the new device to the marketed device?	✓		If NO, note deficiency on FDA_F_09.03.
23. Does the submission contain information about the action taken to comply with voluntary standards?	✓		If NO, note deficiency on FDA_F_09.03.

Third Party Premarket Notification Checklist for Acceptance (Part II)

TÜV SÜD America

Part II - Checklist	YES	NO	Instructions
8. Does the submission contain the "Indications for Use" form?	✓		If YES, indicate page number 4-1. If NO, note deficiency on FDA_F_09.03.
9. Does the submission contain an acceptable 510(k) Summary of Safety and Effectiveness (per 21 CFR 807.92) OR an acceptable 510(k) Statement (per 21 CFR 807.93) that safety and effectiveness information will be made available to any person upon request?	✓		If YES, indicate page number 5-1. If NO, note deficiency on FDA_F_09.03.
10. Does the submission contain photographs of the device if applicable?	✓		If NO, note deficiency on FDA_F_09.03.
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	✓		If NO, note deficiency on FDA_F_09.03.
12. Does the submission identify the device to which equivalence is claimed?	✓		If NO, note deficiency on FDA_F_09.03.
13. If the answer to question 12 is YES, did the applicant identify: a. Predicate device (referred to as marketed device)? b. Legally marketed device (referred to as marketed device)?	✓		K964636 K955020

Third Party Premarket Notification Checklist for Acceptance (Part II)

TÜV SÜD America

Part II - Checklist	YES	NO	Instructions
24. Does the submission contain performance data (can be bench or animal but not clinical), i.e.: Is there performance data for the marketed device? a. Bench testing? b. Animal testing? Is there performance data for the new device? a. Bench testing? b. Animal testing?	 n/a n/a ✓ n/a		 If NO and data are necessary, note deficiency on FDA_F_09.03. If NO and data are necessary, note deficiency on FDA_F_09.03.
25. If the device is labeled as sterile, does the submission contain sterilization data?	✓		If NO, note deficiency on FDA_F_09.03.
26. Does the device incorporate a computer or computer software? a. If YES, is there information about the hardware? b. If YES, is there information about the software?	n/a		
27 a). Is there a specific guidance document for this type of device? Title: _____ _____ _____ _____ _____	n/a		If YES, continue review with checklist from the specific guidance document and return to question 28. If NO, proceed to question 27 b).

Third Party Premarket Notification Checklist for Acceptance (Part II)

TÜV SÜD America

Part II - Checklist	YES	NO	Instructions
27 b). Contact the appropriate ODE Branch Chief to obtain information for reviewing this type of device. Has a summary of this discussion been documented?	N/A		If YES, answer question 28. If NO, do not proceed to question 28; stop review until summary completed.
28. Is this 510(k) sufficiently complete to allow substantive review?	✓		If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms. If NO, note deficiency on FDA_F_09.03.

Letter of Submission Acknowledgment

Date: October 18, 2011

US Medical Innovations, LLC
Mr. Jerome Canady, M.D.
2940 Winter Lake Road
Lakeland, Florida 33803
USA

RE: 510(k) "Canady Vieira Hybrid Plasma™ Scalpel"

Dear Mr. Jerome Canady:

TÜV SÜD Product Service received your 510(k) submission on October 14, 2011 and has initiated the administrative review using the 28-item checklist for acceptance. Upon the completion of the administrative review, we will inform you of the results.

Sincerely,

Alexander Schapovalov
510(k) Third Party Reviewer

Manufacturer' s Authorization Letter

TÜV SÜD America

Date:

TÜV America Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

RE: Authorization for Third Party Review

To Whom It May Concern:

Enclosed is the Premarket Notification 510(k) for the following product Canady Vibra Hybrid Plasma Scalpel manufactured by INEM Equipments

We at US MEDICAL Innovations, LLC (*name of manufacturer*) hereby authorize TÜV America Inc. to submit the enclosed 510(k) to the Food and Drug Administration (FDA) on our behalf, discuss its contents with the FDA, and function as the Third Party Reviewer.

We certify that we have not contacted another Third Party Reviewer to perform the review of this 510(k) submission.

We accept the quote for 510(k) review services including the TÜV America Inc. Terms and Conditions.

Sincerely,

Officer of the Manufacturer
Name and Title JEROME CANADY, M.D., CEO
Phone: 301 270-0147
Fax: 301 270-9849
E-mail: DR JCANADY @ USMEDINNOV.COM

(b)(4)

(b)(4)

TÜV SÜD Product Service GmbH
MHS Foreign Affairs - Alexander Schapovalov
Ridlerstrasse 65
80339 Munich
Germany

To Whom It May Concern:

Please find enclosed US Medical Innovations, LLC. 510(k) Submission for the Canady Vieira Hybrid Plasma Scalpel submitted for Third-Party review.

If you have any questions, please do not hesitate to contact (b)(4) (b)(4) or US Medical Innovations, LLC.

Sincerely,

(b)(4), (b)(6)

(b)(4), (b)(6)

(b)(4)

(b)(4)

5006-0710

Table of Contents

Table of Contents (cont'd)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
10.11.2011		

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
US Medical Innovations, LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(863) 667-1609		
Street Address	**FAX Number *(including area code)***		
2940 Winter Lake Road	(863) 667-1917		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Lakeland	Florida	33803	USA
Contact Name			
Jerome Canady, M.D			
Contact Title	**Contact E-mail Address**		
	drjcanady@usmedinnov.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

(b)(4)

(b)(4)

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K955020	Telescoping Pen Evac ABC	I.C. Medical, Inc.
2	K964636	Force Argon II Argon Enhanced	Valley Lab
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device	Model Number
1	Canady Vieira Hybrid Plasma™ Scalpel	
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GEI	21 CFR 878.4400	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
General, restorative, and Neurological Devices		

Indications *(from labeling)*

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)

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☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No. 60601-2-2	Standards Organization IEC	Standards Title Medical Electrical Equipment Part 2-2: Particular requirements for safety of high frequency surgical equipment.	Version 2006	Date
2	Standards No. 11135: 2007	Standards Organization ISO	Standards Title Sterilization of Health Care Products – Ethylene Oxide Requirements of development validation and routine control of a sterilization process for medical devices Part 1 and Part 2	Version 2007	Date
3	Standards No. 10993-5	Standards Organization AAMI/ANSI/ISO	Standards Title Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity	Version 2009	Date
4	Standards No. 1980	Standards Organization ASTM F	Standards Title Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	Version 2007	Date
5	Standards No. 10993-11	Standards Organization AAMI/ANSI/ISO	Standards Title Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Acute Toxicity	Version 2006	Date
6	Standards No. F756-08	Standards Organization ASTM	Standards Title Standard Practice for Assessment of Hemolytic Properties of Materials. (Biocompatibility)	Version 2008	Date
7	Standards No. ST72	Standards Organization AAMI	Standards Title , Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing. (Sterility)	Version 2002/(R)2010	Date
Please include any additional standards to be cited on a separate page.					

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	33	USP	<85> Bacterial Endotoxins Test. (Sterility)	2010	
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

(b)(4)

(b)(4)

October 13, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

To Whom It May Concern:

US Medical Innovations, LLC has retained (b)(4) (b)(4) *to submit this traditional 510(k) submission for the Canady Vieira Hybrid Plasma™ Scalpel.*

Primary Device:	Electrosurgical cutting and coagulation device and accessories
Regulation Description:	Electrosurgical cutting and coagulation device and accessories.
Product Code:	GEI
Regulation Number:	878.4400
Classification:	II
Panel:	General, restorative, and Neurological Devices

This application is for the Canady Vieira Hybrid Plasma™ Scalpel which can connect to two different Canady generators made by US Medical Innovations. The handpiece uses high frequency (HF) monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with high frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation. There were no modifications to the Canady Plasma™ Electrosurgical System SS-200E/Argon 2 and SS-601MCa/Argon 4 from the previously cleared 510(k) K10069 therefore they are not included with this submission. There also has been no modification particularly to Canady Plasma™ Argon 2 (CPC 2) and Argon 4 Coagulator (CPC 4) cleared April 6, 2011, 510(k) K10069.

Indications for Use Statement

The Hybrid Plasma Scalpel provides enhanced cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

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Question	YES	NO
Is this device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is this device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is this device provided sterile?	X	
Is this device intended for single use?		X
Is this device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is this device implanted?		X

Applicant:
US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803

Contact Person:
Jerome Canady, M.D.
Tel: 863 667-1609
Fax: 863 667-1917

Application Correspondent:
(b)(4), (b)(6)

(b)(4), (b)(6)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

An electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission. If you have any questions regarding this 510(k) submission, please feel free to contact me.

Sincerely,

(b)(4), (b)(6)

(b)(4), (b)(6)

(b)(4)

(b)(4)

Indications for Use

510(k) Number (if known): _____

Device Name: Canady Vieira Hybrid Plasma™ Scalpel

Indications for Use:

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

(per 21 CFR 807.92(c))

1. Applicant

US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803

Contact Person:
Jerome Canady, M.D.
Tel: 863 667-1609
Fax: 863 667-1917

Date Prepared: October 11, 2011

2. Device Name and Classification

Trade Name(s): Canady Vieira Hybrid Plasma™ Scalpel, AW-422552

Common Name: Electrosurgical, cutting & coagulation & accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories

Classification Regulation: 21 CFR 878.4400
Panel: General, Restorative, and Neurological Devices
Product Code: GEI
Class: II

3. Predicate Devices

The Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent to the following devices:

510(k) Number	Device	Manufacturer
K955020	Telescoping Pen Evac ABC	I.C. Medical, Inc.
K964636	Force Argon II Argon Enhanced	Valley Lab

4. Description of the Device

The Canady Vieira Hybrid Plasma™ Scalpel is an accessory multi-functional electrosurgical handpiece used for open surgical procedures where monopolar radio frequency electrosurgical handpieces (cutting, coagulation) is normally used. The handpiece uses radio frequency (RF)

monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with radio frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation.

The handpiece consists of three major components: Handle, Telescoping Nozzle, and Electrode. The insulated handle encases the radio frequency (RF) current and gas tubing for controlling the flow of argon gas and activation of RF current for the device. RF current is activated by two push buttons yellow (standard CUT mode) and blue (standard COAG mode) which are top of the handle. Argon gas is delivered via the handle by activating a third push button (purple) which is also on top of the handle. The electrode tip has 4 modes of operation and as shown in the below table, this words appear depending on the mode of operation that is necessary.

Table 5-1

Canady Vieira Hybrid Plasma™ Scalpel Mode	Operation being performed
CUT	Cuts Tissue
COAG	Coagulates Tissue
ARGON PLASMA COAG	Coagulates Tissue
CANADY VIEIRA HYBRID PLASMA CUT	Cuts Tissue

Depending on the RF current mode (CUT or COAG), the handpiece can function in the following argon modes: HYBRID PLASMA CUT – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the CUT mode. Hybrid Argon Plasma Cut mode will cut and coagulate the tissue at the same time. ARGON PLASMA COAGULATION – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the COAG mode. Argon Plasma Coagulation will coagulate the tissue. The Canady Vieira Hybrid Plasma™ Scalpel is an accessory that is used with the Argon 2 (CPC2) and Argon 4 (CPC4) generators, previously cleared by FDA. These generators provide a controlled flow of argon to the electrosurgical handpiece during Hybrid Plasma Cutting or Argon Plasma Coagulation modes. The Physician manually sets the flow rate on the Plasma coagulator. The telescoping nozzle can be extended or shortened over the electrode as desired when the surgeon is performing argon procedures.

5. Indications for Use (IFU)

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

6. Summary of Performance Data

Biocompatibility Testing

Biocompatibility testing was performed to validate the patient contacting material used for the Canady Vieira Hybrid Plasma™ Scalpel. These tests were conducted to meet ISO 10993-1 and USP requirements.

Performance Testing – Bench Studies

Testing was completed to ensure that the Canady Vieira Plasma ™ Scalpel meets the requirements of IEC 60601-1-2 and IEC 60601-2-2 and to ensure that it is compatible with the Canady Plasma Argon 2 and Argon 4 Electrosurgical Generators SS-200-E and SS-601-MCa. Bench Testing was also performed to ensure cutting and coagulation using the device, as well as shelf life and sterility testing.

Performance Testing – Clinical Studies

No Clinical studies were performed for the submission of this 510(k).

7. Safety & Effectiveness

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A
Indications for Use	Hybrid Plasma provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Reusable	No	Yes	No	None
Sterilization Method	EO	EO	EO	None
Needle tip length	2.5cm	2.5cm	2.5cm	None
Buttons on scalpel	3 buttons	3 buttons	3 buttons	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

As demonstrated in the above table the Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent to the predicate devices listed in this 510(k) submission. The Canady Vieira Hybrid Plasma ™ Scalpel compared to the predicate devices does not raise issues with regards to safety and effectiveness.

Section 6 – Truthful and Accuracy Statement

Premarket Notification Truthful and Accuracy Statement
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as **manager** for US Medical Innovations, LLC . I believe to the best of my knowledge, that all data and information submitted in the premarket nofification are truthful and accurate and that no material fact has been omitted.

Jerome Canady, M.D.

10.05.2011

10.05.2011

Class III Summary and Certification

This section of the 510(k) Submission is **not applicable.**

Reason for Non-Applicability:

The Canady Vieira Hybrid Plasma™ Scalpel is classified as an"electrosurgical cutting and coagulation device and accessories" under regulation 21CFR 878.4400, within the General, restorative, and Neurological Panel (Product Code: GEI). It is therefore classified as a Class II device, for which the Class III Summary and Certification information, in accordance with 21CFR 807.87(j) and 807.94, is not required.

8. Financial Certification or Disclosure Statement

Not Applicable to the 510(k).

9. Required Elements for a Declaration of Conformity to a Recognized Standard

In the development of the Canady Vieira Hybrid Plasma ™ Scalpel U.S., Medical Innovation, LLC has ensured that the scalpel is in compliance with all of the following recognized standards. The list of all recognized Consensus Standards can be found in Section 2. All reports certifying that the device meets the standard are locate din the applicable appendices.

Standards No	Standard Organization	Standard title	Version	Date
60601-1	IEC	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	2005	
60601-1-2	IEC	Medical electrical equipment, Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	2001 A1: 2004	
60601-2-2	IEC	Medical Electrical Equipment Part 2-2: Particular requirements or safety of high frequency surgical equipment	2006	
11135	ISO	Sterilization of Health Care Products-Ethylene Oxide Requirements of development validation of a sterilization process for medical devices Part 1 and Part 2	2007	
10993-5	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity	2009	
1980	ASTM F	Standard Guide for Accelerated Aging for Medical Devices	2007	
10993-10	AAMI/ANSI/ISO	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	2010	
10993-11	AAMI/ANSI/ISO	Biological Evaluation of medical Devices-Part 11: Test for Systemic Acute Toxicity	2006	
FT756-08	ASTM	Standard Practice for Assessment of Hemolytic Properties of Materials. (Biocompatibility)	2008	
ST72	AAMI	Bacterial endotoxins-Test methodologies, routine monitoring, and alternatives to batch testing. (Sterility)	2002(R) 2010	
33	USP	<85> Bacterial Endotoxins Test (Sterility)	2010	

For all Standards used in the Canady Vieira Hybrid Plasma ™ Scalpel

which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).		
d. An identification, for each consensus standard, of any requirements that were not applicable to the device.	N/A	
e. A specification of any deviations from each applicable standard that were applied.	N/A	
f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.	N/A	
g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.	Yes	

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-2 2006 Medical Electrical Equipment Part 2-2: Particular requirements for safety of high frequency surgical equi

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#6-197	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-2 Medical Electrical Equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 2-2	Particular requirements for safety of high frequency surgical equipment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

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• Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135: 2007 Sterilization of Health Care Products – Ethylene Oxide Requirements of development validation and routine contr

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11135: 2007 Sterilization of Health Care Products – Ethylene Oxide Requirements of development validation and routine contr

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-5:2009- Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 10993-5:2009- Biological Evaluation of Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 5	Tests for in Vitro Cytotoxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: ISO 11607

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-11: 2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Acute Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 10993-11: 2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Acute Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 11	Tests for Systemic Acute Toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F756-08, 2008 Standard Practice for Assessment of Hemolytic Properties of Materials. (Biocompatibility)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-154	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F756-08, 2008 Standard Practice for Assessment of Hemolytic Properties of Materials. (Biocompatibility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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DESCRIPTION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP 33:2010, <85> Bacterial Endotoxins Test. (Sterility)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-303	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
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Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
USP 33:2010, <85> Bacterial Endotoxins Test. (Sterility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ST72:2002/(R)2010, Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing. (Sterilit

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-292	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: USP 85

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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SUMMARY REPORT TABLE

STANDARD TITLE
AAMI ST72:2002/(R)2010, Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing. (Sterilit

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
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Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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10. Executive Summary

10.1 Device Description

The Canady Vieira Hybrid Plasma™ Scalpel is an accessory multi-functional electrosurgical handpiece used for open surgical procedures where monopolar radio frequency electrosurgical handpieces (cutting, coagulation) is normally used. The handpiece uses radio frequency (RF) monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with radio frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation.

The handpiece consists of three major components: Handle, Telescoping Nozzle, and Electrode. The insulated handle encases the radio frequency (RF) current and gas tubing for controlling the flow of argon gas and activation of RF current for the device. RF current is activated by two push buttons yellow (standard CUT mode) and blue (standard COAG mode) which are top of the handle. Argon gas is delivered via the handle by activating a third push button (purple) which is also on top of the handle. The electrode tip has 4 modes of operation and as shown in the below table, this words appear depending on the mode of operation that is necessary.

Table 10-1

Canady Vieira Hybrid Plasma™ Scalpel Mode	Operation being performed
CUT	Cuts Tissue
COAG	Coagulates Tissue
ARGON PLASMA COAG	Coagulates Tissue
CANADY VIEIRA HYBRID PLASMA CUT	Cuts Tissue

Depending on the RF current mode (CUT or COAG), the handpiece can function in the following argon modes: HYBRID PLASMA CUT – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the CUT mode. Hybrid Argon Plasma Cut mode will cut and coagulate the tissue at the same time. ARGON PLASMA COAGULATION – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the COAG mode. Argon Plasma Coagulation will coagulate the tissue. The Canady Vieira Hybrid Plasma™ Scalpel is an accessory that is used with the Argon 2 (CPC2) and Argon 4 (CPC4) generators, previously cleared by FDA. These generators provide a controlled flow of argon to the electrosurgical handpiece during Hybrid Plasma Cutting or Argon Plasma Coagulation modes. The Physician manually sets the flow rate on the Plasma coagulator. The telescoping nozzle can be extended or shortened over the electrode as desired when the surgeon is performing argon procedures.

Canady Vieira Hybrid Plasma™ Scalpel is intended to be only used with Canady Plasma™ Electrosurgical System SS-200E/Argon 2 and SS-601MCa/Argon 4 previously cleared under 510(k) K100669.

The handle power cord is approximately ten (10) feet in length and incorporates a 3-prong electrical plug. The insulation of the insulated handle and power cord meets the requirements

for IEC 60601-2-2 as described in **Section 17** of this 510(k) and can only be used with the 2 US Medical Innovations, LLC generators, Argon 2 (CPC 2) and Argon 4 (CPC4).

10.2 Indications for Use

The Hybrid Plasma Scalpel provides enhanced cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

10.3 Performance Testing

Biocompatibility testing was performed to validate the patient contacting material used for the Canady Vieira Hybrid Plasma™ Scalpel. These tests were conducted in accordance with ASTM F756-08 and ISO 10993 which included selection of tests for interactions with Blood Hemolysis and Blood Compatibility, In Vitro Cytotoxicity, Sensitization, and Intracutaneous and Systemic Toxicity. All biocompatibility tests passed and proved that the device material is safe for patient contact based on the indication for use. All recognized consensus standards that were used for Biocompatibility are listed in the applicable US FDA Form 3654 and on the CDRH Cover Sheet in **Section 2** of this 510(k) application. A summary is provided in **Section 15** with regards to Biocompatibility and the actually reports are listed in **Appendices 15**.

The devices also comply with NBR IEC 60601-1 Standard, Electromedical equipment – Part 1 – General requirements for safety, NBR IEC 60601 – 2 – 2 Electromedical equipment – Part 2 – 2: Particular requirements for the safety of high frequency surgical equipment, NBR IEC 60601 – 1 – 2, Electromedical equipment – Part 1 – 2: Collateral standard: Electromagnetic compatibility – Requirements and test , a summary is provided in Section 17 and the electrical safety reports are in **Appendices 17**.

US Medical Innovations also performed accelerated aging studies per ASTM F1980-07, the device has a shelf life of 3 years and has an expiration date listed on the label based on this shelf life data. Sterility test performed met the requirements of ISO 11135 USP 85, and ANSI/AAMI ST72. All shelf life and sterility tests passed. All recognized consensus standards that were used for these test are listed in the applicable US FDA Form 3654 and on the CDRH Cover Sheet in **Section 2** of this 510(k) application. A summary is provided in **Section 14** with regards to Sterility and Shelf life the actually reports are listed in **Appendices 14**.

Performance Testing- Animal
Animal testing was performed to ensure that the device met its intended purpose of cutting and coagulating. The detail report is located in **Appendix 18a**.
Performance Testing – Clinical
No Clinical studies were performed for the submission of this 510(k).

Risk Analysis
A comprehensive Risk Analysis (RA) was conducted by the manufacturer (US Medical Innovations, LLC) to identify the inherent risks associated with the Canady Vieira Hybrid Plasma™ Scalpel. US Medical Innovations, LLC identified all risks and then ranked them as to their severity and likelihood of occurrence; the type of harm they could cause; and how the risks

could be mitigated and/or dealt with if they occurred (e.g., WARNING statement in the User's Guide.) Based on this analysis it was concluded that the benefits of the Canady Vieira Hybrid Plasma™ Scalpel clearly outweighed the potential risks.

10.4 Substantial Equivalence Table

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A
Indications for Use	Hybrid Plasma provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Reusable	No	Yes	No	None
Sterilization Method	EO	EO	EO	None
Needle tip length	2.5cm	2.5cm	2.5cm	None
Buttons on scalpel	3 buttons	3 buttons	3 buttons	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

10.5 Substantial Equivalence Discussion

The Canady Vieira Hybrid Plasma™ Scalpel is classified as a Class II device under FDA Product Code GEI under 21 CFR 878.4400. This device has no significant difference in intended use, technology, materials, performance, and sterilization method compared to the predicate devices. As mentioned in the above section 10.4 all devices use the same materials and are monopolar devices . In some instances the output wattage is lower than the predicates devices thus reducing the safety concerns. The indications for use is also similar amongst all three devices. The Canady Vieira Plasma™ Scalpel and the predicate devices do not raise issues of safety and effectiveness.

11. Device Description

11.1 Indications for Use

The Hybrid Plasma Scalpel provides enhanced cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

11.2 Device Description

The Canady Vieira Hybrid Plasma™ Scalpel is an accessory multi-functional electrosurgical handpiece used for open surgical procedures where monopolar radio frequency electrosurgical handpieces (cutting, coagulation) is normally used. The handpiece is a single use device and uses radio frequency (RF) monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with radio frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation. The electrode is built into the scalpel itself. In **Figure 11-1 and 11-2** are pictures provided to show the device . A more detail description of the use of the device can be found in the User Manual for Argon 2 and Argon 4 Generator Attachment (**Appendices 13a and 13b**).

Figure 11-1: Handpiece Position for the Canady Hybrid Vieira Plasma™ Scalpel

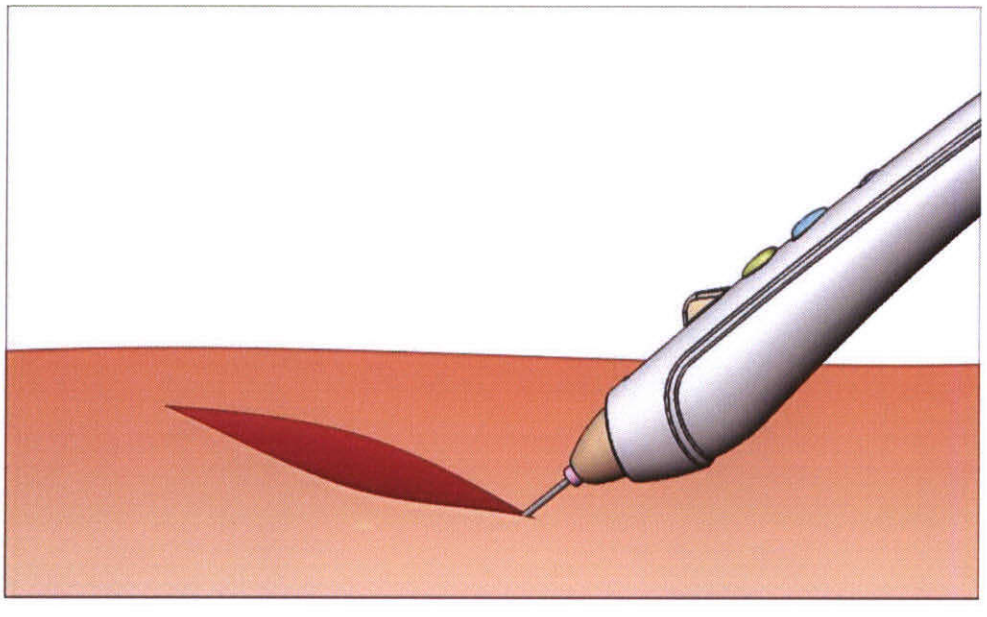
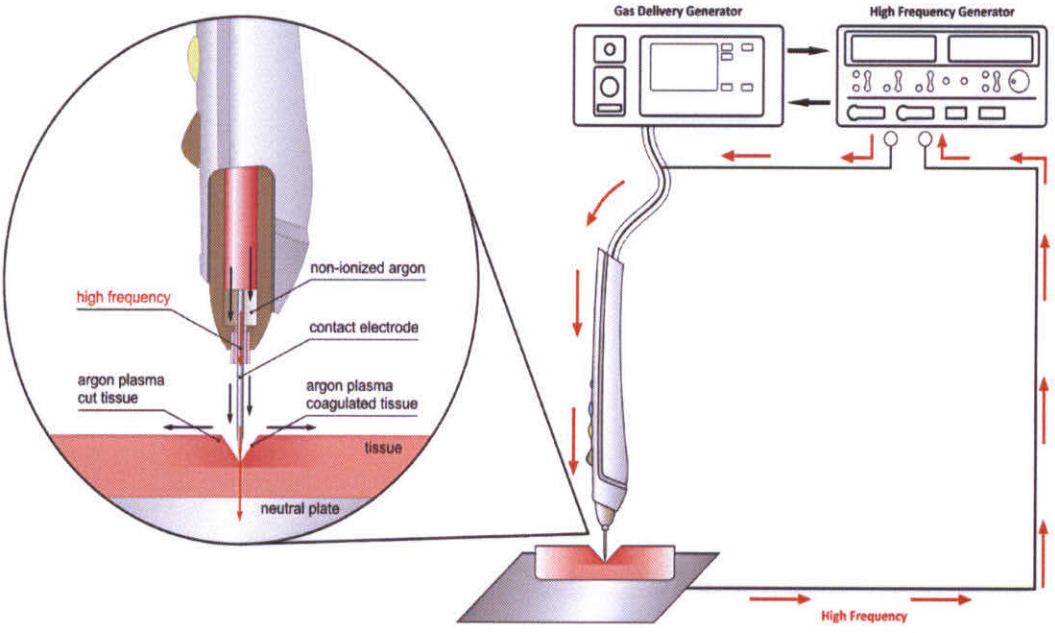


Figure 11-2: Detailed View of the Canady Vieira Hybrid Plasma™ Scalpel



The handpiece consists of three major components: Handle, Telescoping Nozzle, and Electrode. The insulated handle encases the radio frequency (RF) current and gas tubing for controlling the flow of argon gas and activation of RF current for the device. RF current is activated by two push buttons yellow (standard CUT mode) and blue (standard COAG mode) which are top of the handle. Argon gas is delivered via the handle by activating a third push button (purple) which is also on top of the handle. The electrode tip has 4 modes of operation and as shown in the below table, this words appear depending on the mode of operation that is necessary.

Table 10-1

Canady Vieira Hybrid Plasma™ Scalpel Mode	Operation being performed
CUT	Cuts Tissue
COAG	Coagulates Tissue
ARGON PLASMA COAG	Coagulates Tissue
CANADY VIEIRA HYBRID PLASMA CUT	Cuts Tissue

Depending on the RF current mode (CUT or COAG), the handpiece can function in the following argon modes: HYBRID PLASMA CUT – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the CUT mode. Hybrid Argon Plasma Cut mode will cut and coagulate the tissue at the same time. ARGON PLASMA COAGULATION – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the COAG mode. Argon Plasma Coagulation will coagulate the tissue. The Canady Vieira Hybrid Plasma™ Scalpel is an accessory that is used with the Argon 2 (CPC2) and Argon 4 (CPC4) generators, previously cleared by

FDA. These generators provide a controlled flow of argon to the electrosurgical handpiece during Hybrid Plasma Cutting or Argon Plasma Coagulation modes. The Physician manually sets the flow rate on the Plasma coagulator. The telescoping nozzle can be extended or shortened over the electrode as desired when the surgeon is performing argon procedures.

11.3 Materials and Device Drawings

Device Material

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None

Packaging Material

The packaging utilized for packaging the Canady Vieira Hybrid Plasma Scalpel is a sealed envelope for sterilization (surgical grade material). One side of this envelope is made of polyethylene and the other made of surgical grade paper. The scalpel will be sterilized following finished device packaging. After the finished scalpel is inserted in the envelope, the primary package is sealed, and the final device is sterilized via Ethylene Oxide (EtO). This is the same material and sterilization method that was cleared in K100669 for the Canady Plasma Probes in April 2011.

(b)(4)

(b)(4)

include resistance and reliability of the packaging material, according to ASTM F88 "Standard Test Method for Seal Strength of Flexible Barrier Materials" and ASTM D903 " Standard Test Method for Peel or Stripping Strength of Adhesive Bonds." The packaging material specification is included **Appendix 11b.**

For a more detail review of the device components, a device drawing is located in **Appendix 11a.**

11.4 Product Specifications

The Canady Vieira Hyrbid Plasma™ Scalpel is an accessory that is used with the Argon 2 (CPC2) and Argon 4 (CPC4) Generators. In the Argon 2 and Argon 4 User Manuals a more detailed description is provided to explain the use of the device and how the accessory connects to the Generator. **See Appendices 13a and 13b**.

Page 127 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
(b)(4)

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Embalagens Médico-Hospitalares

Instructions of Use

Envelope for Sterilization made of Polypropylene
Models: Tubular and Envelope
CIPAMED Medical Packages Ltda.

Distributor in Brazil:
CIPAMED Medical Packages Ltda.
CNPJ: 03.471.879/0001-48
Street Antonio Moisés Saadi, 710–
Industrial Park Lagoinha
Ribeirão Preto – SP
CEP: 14095-230
Phone: (16) 3965 6112
Fax: (16) 3965 6212
www.cipamed.com.br
e-mail: cipamed@cipamed.com.br

Manufacturer:
CIPAMED Medical Packages Ltda.
CNPJ: 03.471.879/0001-48
Street Antonio Moisés Saadi, 710–
Industrial Park Lagoinha
Ribeirão Preto – SP
CEP: 14095-230
Phone: (16) 3965 6112
Fax: (16) 3965 6212
www.cipamed.com.br
e-mail: cipamed@cipamed.com.br

Batch Number: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

ANVISA Registration Number: WWWWWWWWWWWWWWWWWWWWWW

Technical Responsible: Paulo Henrique Savoia – CRQ: 04223076

Content:

Tubular

Thermal Sealant Package:

Size of mm X m: With 50 to 600 mm of width by 30, 50, 80, 100 and 200 meters of length in box containing from 12 to 1 unit respectively.

Thermal Sealant Package with fold:

Size of mm X m: With 100 X 40 X 100 to 400 X 90 X 100 in box containing 12 to 1 unit respectively

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Instructions of Use

Envelope

Thermal Sealant Package: Size of mm X mm: With 50 X 100 to 600 X 600 in box of 5.000 to 1.000 units respectively.

Thermal Sealant Package with fold:

Size of mm X mm: With 100 X 50 X 300 to 400 X 80 X 550 in box of 5.000 to 1.000 units respectively.

Self-Sealing Envelopes

Size of mm X mm: With 50 X 120 to 250 X 410

1. Product Identification

The packages are made of surgical grade paper that have a controlled bacterial barrier with a film laminate of polyester and polypropylene available in configurations of tubular and thermal sealant envelopes and self-sealing envelopes, with sealing of thermal fusion. Developed for the packaging of dental-medical-hospital articles that will be subjected to sterilization processes by saturated steam or ETO gas.

Technical Features

The envelopes and tubulars for sterilization are products made by a area of surgical paper with gramature of 60g/m2 or 70g/m2 with variation of + / - 4%, according to NBR NM ISO-536 and barrier properties bacteriological characteristics obtained from:

- Composition of the paper - mixtures of long and short fibers
- Controlled pore sizes of paper. (The diameter of the pores of the paper has the function of allowing a sterilizing agent and block entry of bacteria)
- Resistance to liquid.
- Mechanical strength.

The other area is composed of polyester film laminated with polypropylene that have transparency properties which provides visibility of contents and sealing (thermal fusion), the film laminate provides great elasticity and is stable enough to withstand the sterilization process, providing protection against contamination.

Film Features:

- Polyester with 12µ with 18g/m^2
- Polypropylene with 40µ with 36g/m^2
- Adhesive sterilizable 3g/m^2
- Total gramature 57 g/m^2
- Thickness 52µ
- Heat resistance 140 ° C

The raw materials used for the manufacture of tubular and envelope thermal sealants meet the requirements of ABNT - NBR 14990.

- Sealing of the upper edges of the thermal sealant envelopes and self-sealing envelopes attenuate the accumulation of dust in the area of opening, reducing the risk of contamination when opening the package.
- The indicators for saturated steam and ethylene oxide gas (ETO) are subject to the same conditions for the sterilization of packaged products, the printing is located within the sealing area to prevent migration of ink to into the packaging.

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• The envelopes and tubulars are characterized by a special design (seal filleted) on the sealing area which makes its opening process with an indication of right direction.

• The laminated blue film supports extraordinarily well the tensions of manipulation. Could present a fold in the longitudinal direction that facilitates the packaging of goods larger.

• Packaged products can be easily identified thanks to the transparent film.

• Once sealed, the laminated blue film produces a contrast in the area of sealing that allows visually detect any possibility of deficiency in the sealing process that could compromise the integrity of package.

• The sealing is compound with narrow channels multi-linear which are extremely resistant to the stresses that are subjected during handling and packaging to the sterilization process and allows aseptic opening, if used the correct technique for opening.

• The width of the sealing area is specified from 10 to 12 mm.

• The method used to determine the resistance of sealing is the tensile test seal. (ASTM - F88 and ASTM - D903 DA / NBR: 14990-1).

Printing

The printing process is made by a flexographic system in the sealing area to avoid migration of ink to into the packaging.

• Text is printed in blue, resistant to sterilization temperature without suffering any alteration and contains no toxic substances according to technical report from the supplier.

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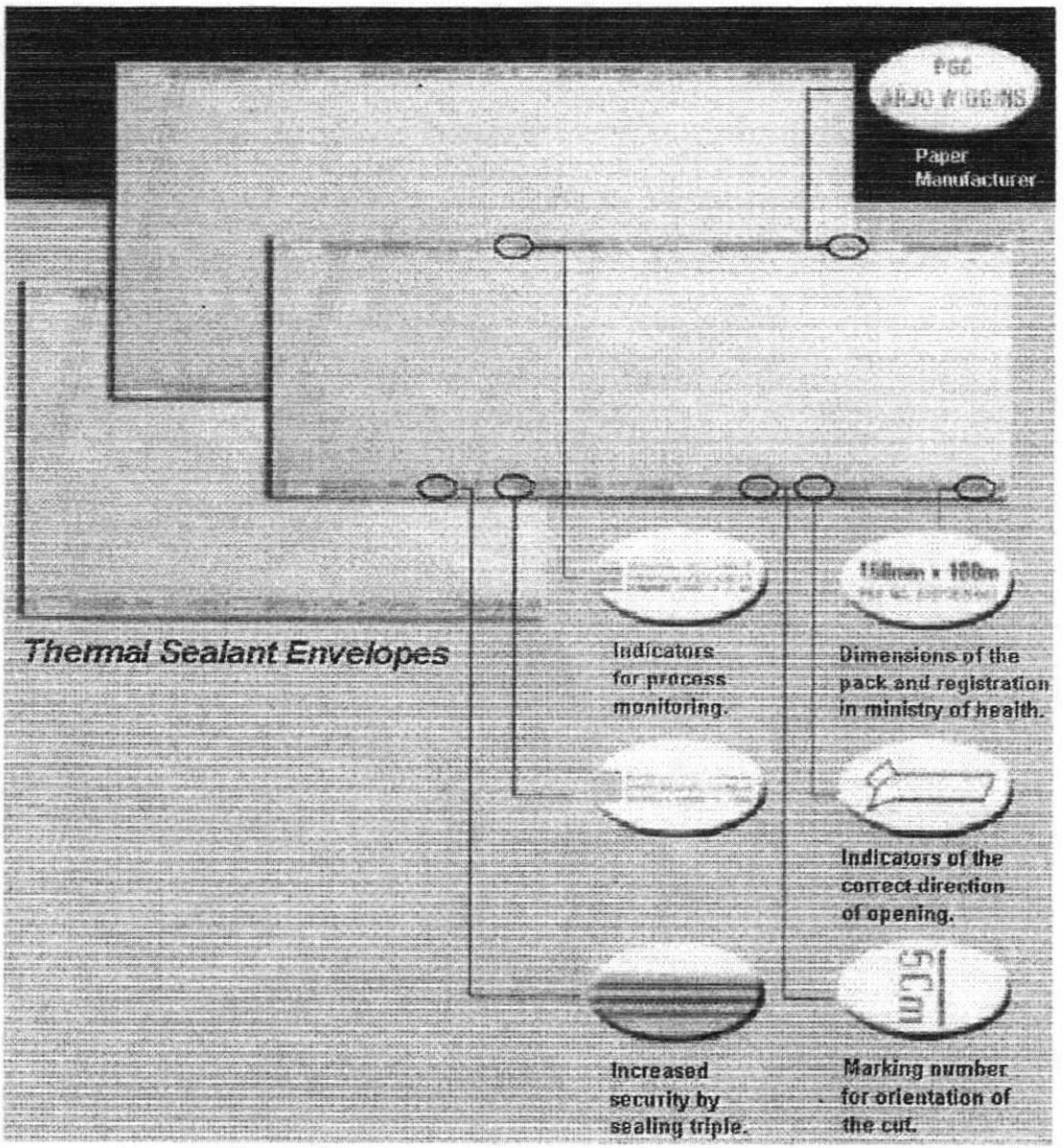
Instructions of Use

• The ink of chemical indicator for sterilization is sensitive to recognize the passage through the sterilization process with clear visual evidence when exposed to the process, measuring 100 mm^2 according to NBR: 14990-7.

The processing conditions could vary considerably due to the type of sterilizer. If the critical values vary too much, maybe the color change could vary too, however the indication of processing will still be present at the sterilizers.

Graphic Information



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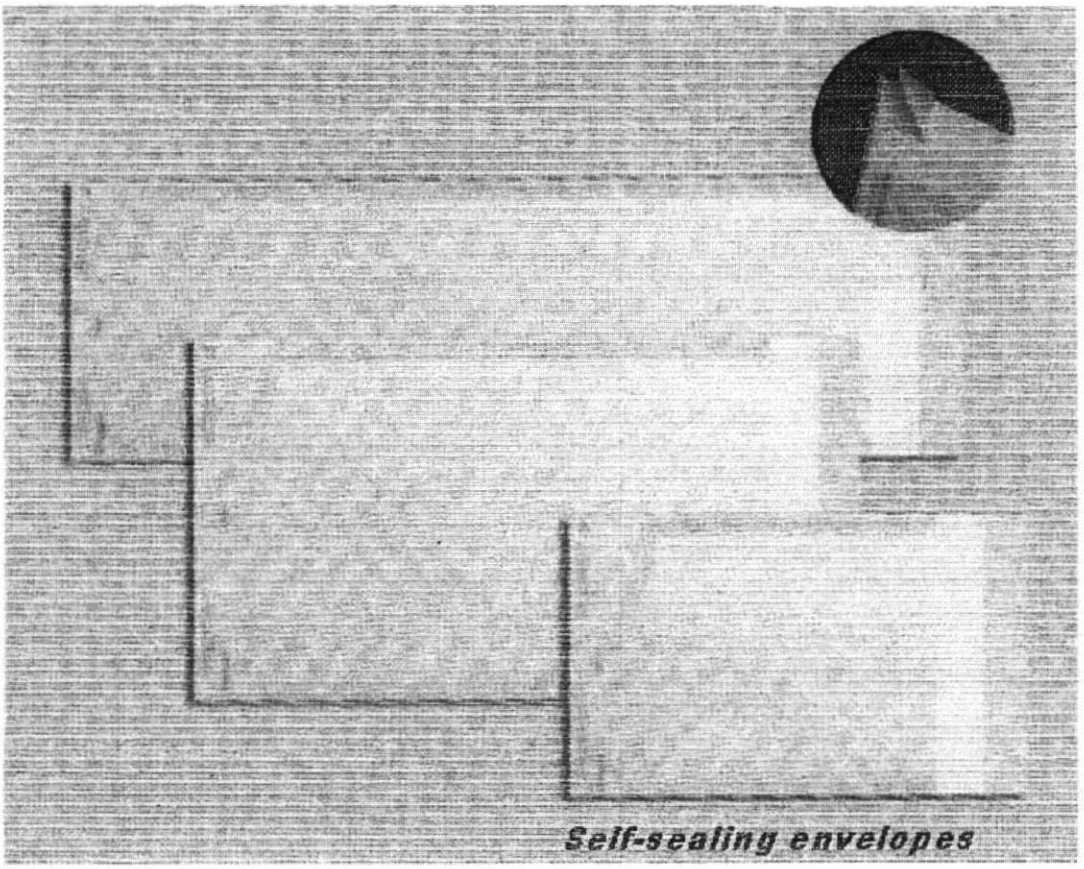
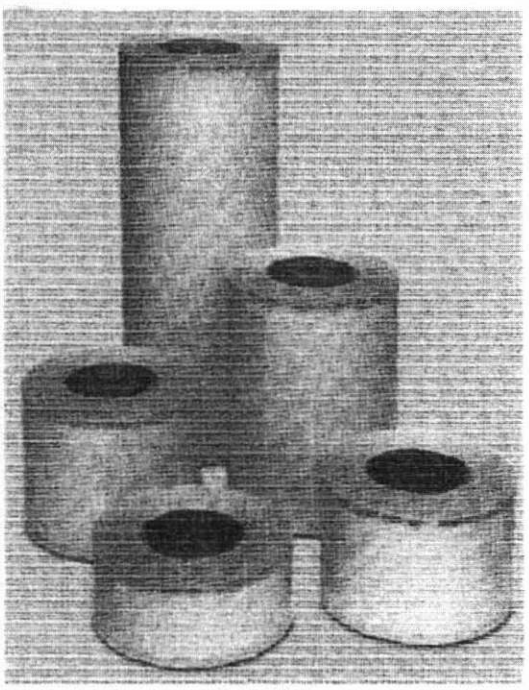
Emballages Médico-Hospitaliers

Instructions of Use





Tubular

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Embalagens Médico-Hospitalares

2. Special conditions of Storage, Conservation and/or Handling of the product.

- They must be stored and transported under cover of dust, heat, sunlight and chemical contaminants.
- Must be kept in its shipping container until ready to use to avoid damage to the material.
- They must be kept away from moisture.
- Store at room temperature.
- Store products in shelves or platforms in way to avoid contact with the floor. Keep the products away from the walls.

3. Instructions of Use

- To seal the package (thermal sealant tubular or envelopes) always use a sealer that provides a sealing width of at least 8mm.
- The distance between the sealing and package edge (Tubular) should be approximately 3 cm to facilitate opening the package and avoid disruptions of the package.
- Single use material. The reuse commits the material sterility.
- The quantities of instruments to be placed on packages should be compatible with the dimensions of the packages. If the quantities are not compatible, exist the risk of disruption of the structures of packaging.
- Proceed with protection of sharp instruments to avoid breaking the packages.
- Proceed with the disposition of the packages side by side (Paper with Paper and Film with Film) in the autoclave to promote better circulation of the sterilizing agent.

• Check after the sterilization process the clear color change of chemical indicators printed on the packaging. These parameters are for the differentiation of the packages that have been subjected to sterilization processes. Note: The process indicators do not ensure sterilization parameters.

• Promote opening of the packages as printed on packages (right direction of opening).

• Self-sealing envelope: After the introduction of material to be sterilized, remove the protective tape from the adhesive and make the fold on the dotted line in a continuously way sealing the package and avoid during the sealing process the forming of channels or wrinkles around the adhesive area. (closing with special adhesive tape resistant to high temperature).

4. Warnings and / or precautions to be taken

• Do not utilize packages if they have been damaged.
• Do not reutilize the packages.
• Do not utilize the packages if the chemical indicators didn't change color after the sterilization process.
• The packages handled in aseptic areas should be handled by trained personnel to avoid contamination.

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Instructions of Use

TERM OF LEGAL WARRANTY

(According to Code of Protection and defense of Consumer: Law 8078 of 11 September 1990)

The company **CIPAMED Medical Packages Ltda**, pursuant to Article 26 of Law 8078 of 11 September 1990, comes through this legal instrument, ensure the right of the consumer in complaint about the visible defects or easily detectable of all the products imported and marketed by her, within 90 days, counting on the effective delivery date of the products. In case of latent defect, the statutory limitation period begins at the moment it is evidenced the defect as provided in Paragraph 3 of Art.26 of Law 8078.

For the Term of this Legal Guarantee take effect, consumers should observe the conditions below:

Do not allow unauthorized persons to perform maintenance of equipment or materials in question.

Do not allow the abuse and misuse of materials or equipment in question.

Follow in detail all the guidelines for use and care of cleaning and maintenance described in the User Manual or Instructions for Use.

The parts and pieces that will suffer wear due to use of materials or equipment are not covered by this agreement Statutory Warranty if the defect is unclaimed after the deadline specified by the manufacturer for regular replacement of these items.

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Instructions of Use

We declare that the information presented in this model of Instructions for Use is true.

Paulo Henrique Savoia

Paulo Henrique Savoia
CRQ: 04223076
Technical Responsible

12. Substantial Equivalence Section

12.1 Overview

The Canady Vieira Hybrid Plasma™ Scalpel is an accessory multi-functional electrosurgical handpiece used for open surgical procedures where monopolar radio frequency electrosurgical handpieces (cutting, coagulation) is normally used. The handpiece uses radio frequency (RF) monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with radio frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation.

The Scalpel is a single use device and is used as an accessory to the Canady Plasma™ Electrosurgical System SS-200E/Argon 2 (CPC2) and SS-601MCa/Argon 4 (CPC4) from the previously cleared 510(k) K100669, therefore they are not included with this submission. There also has been no modification particularly to Canady Plasma™ Argon 2 (CPC 2) and Argon 4 Coagulator (CPC 4) cleared April 6, 2011, 510(k) K100669. CPC 2 and CPC4 which are equivalent to the Force Argon™ II Argon Enhanced Electrosurgical System (K964636) and Valleylab "Force GSU handset" E2522H.

12.2 Indications for Use

The Hybrid Plasma Scalpel provides enhanced cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

12.3 Performance Testing

Biocompatibility Testing

Biocompatibility testing was performed to validate the patient contacting material used for the Canady Vieira Hybrid Plasma™ Scalpel. These tests were conducted in accordance with ASTM F756-08 and ISO 10993 which included selection of tests for interactions with Blood Hemolysis and Blood Compatibility, In Vitro Cytotoxicity, and Intracutaneous, Sensitization, and Systemic Toxicity. All biocompatibility tests passed and proved that the device material is safe for patient contact based on the indication for use. All recognized consensus standards that were used for Biocompatibility are listed in the applicable US FDA Form 3654 and on the CDRH Cover Sheet in **Section 2** of this 510(k) application. A summary is provided in **Section 15** with regards to Biocompatibility and the actually reports are listed in **Appendices 15**.

Electrical Safety Testing

The Canady Vieira Hybrid Plasma ™ Scalpel complies with IEC 60601-1-2 Int. 1 Third Edition/I-SH 01:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Interpretation as well as with IEC 60601-1 Standard, Electromedical equipment – Part 1 – General requirements for safety, NBR IEC 60601 – 2 – 2 Electromedical equipment –Part 2 – 2: Particular

requirements for the safety of high frequency surgical equipment and was conducted by an outside laboratory, see **Appendices 17** for information.

Shelf Life and Sterility Testing

US Medical Innovations also performed accelerated aging studies per ASTM F1980-07, the device has a shelf life of 3 years and has an expiration date listed on the label based on this shelf life data. Sterility test performed met the requirements of ISO 11135 USP 85, and ANSI/AAMI ST72. All shelf life and sterility tests passed. All recognized consensus standards that were used for these tests are listed in the applicable US FDA Form 3654 and on the CDRH Cover Sheet in **Section 2** of this 510(k) application. A summary is provided in **Section 14** with regards to Sterility and Shelf life the actually reports are listed in **Appendices 14**.

Performance Testing- Animal

Animal testing was performed to ensure that the device met its intended purpose of cutting and (b)(4) (b)(4) The detail report is located in **Appendix**

Performance Testing – Clinical

No Clinical studies were performed for the submission of this 510(k).

Risk Analysis

A comprehensive Risk Analysis (RA) was conducted by the manufacturer (US Medical Innovations, LLC) to identify the inherent risks associated with the Viberect. Reflexonic identified all risks and then ranked them as to their severity and likelihood of occurrence; the type of harm they could cause; and how the risks could be mitigated and/or dealt with if they occurred (e.g., WARNING statement in the User's Guide.) Based on this analysis it was concluded that the benefits of the Canady Vieira Plasma™ Scalpel clearly outweighed the potential risks.

12.4 Substantial Equivalence Table

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A

Indications for Use	Hybrid Plasma provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Reusable	No	Yes	No	None
Sterilization Method	EO	EO	EO	None
Needle tip length	2.5cm	2.5cm	2.5cm	None
Buttons on scalpel	3 buttons	3 buttons	3 buttons	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

12.5 Substantial Equivalence Discussion

The Canady Vieira Hybrid Plasma™ Scalpel is classified as a Class II device under FDA Product Code GEI under 21 CFR 878.4400. This device has no significant difference in intended use, technology, materials, performance, and sterilization method compared to the predicate devices. As mentioned in the above section 10.4 all devices use the same materials and are monopolar devices. The Gas Flow rate is different between the Canady Vieria Hybrid Plasma and the predicate devices. The output wattage is lower than the predicates devices thus reducing the safety concerns, however, surgeons will be using the scalpel within the range of the predicate devices because certain flow rates are necessary for effective cutting and coagulating based on the surgeon. The indications for use is also similar amongst all three devices. The Canady Vieira Plasma™ Scalpel and the predicate devices do not raise issues of safety and effectiveness.

13. Proposed Labeling

As part of this 510(k) application, US Medical Innovations, LLC has included the following labels:

User Manual Argon 2 rev 01 and User Manual Argon 4 rev 01 October 2011 have been updated to include the Canady Vieira Hybrid Plasma ™ Scalpel. This is the only change to the user manuals since the July 2010 rev 01.

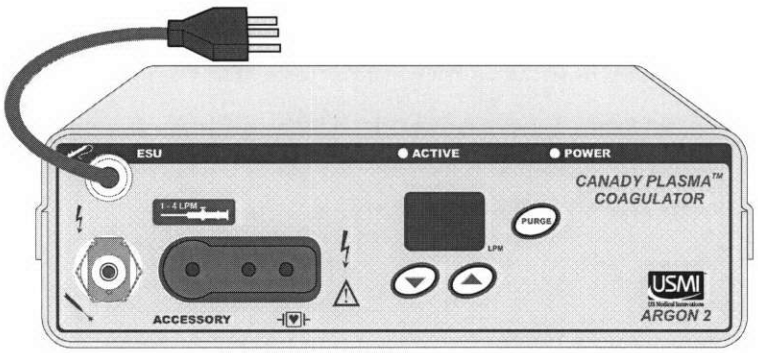
The materials used for the packaging are described in **section 11** of this 510(k)

Appendix 13a- User Manual Argon 2
Appendix 13b- User Manual Argon 4
Appendix 13c- WEM Canady Vieira Hybrid Plasma™ Scalpel Safety Sheet
Appendix 13d- Box Label, Canady Vieira Hybrid Plasma™ Scalpel
Appendix 13e- Part 1 Inner Label, Canady Vieira Hybrid Plasma™ Scalpel
Appendix 13f- Part 2 Inner Label, Canady Vieira Hybrid Plasma™ Scalpel
Appendix 13g- Canady Vieira Hybrid Plasma™ Scalpel Brochure

CANADY PLASMA™ COAGULATOR

Model ARGON 2

OPERATION MANUAL



US Medical Innovations

OPERATION MANUAL

Foreword

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the Canady Plasma™ Coagulator model Argon 2. Additional technical information is available in the Service Manual of Canady Plasma™ Coagulator model Argon 2.

Precaution:

Federal (USA) law restricts this device to sale, distribution or use by or on the order of a physician.

Equipment covered in this manual:

Canady Plasma™ Coagulator – Model Argon 2 is distributed by US Medical Innovations, LLC

Nominal Supply Voltage
100 to 240 VAC with automatic voltage selection 45 / 65 Hz

Trademark acknowledgements:
USMI Logo is the trademark of US Medical Innovations, LLC

For information call:
US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803
Telephone # 863 667-1609 - Fax # 863 667-1917
Website: www.usmedinnovations.com

Customer Service
US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803
Telephone # 863 667-1609 - Fax # 863 667-1917

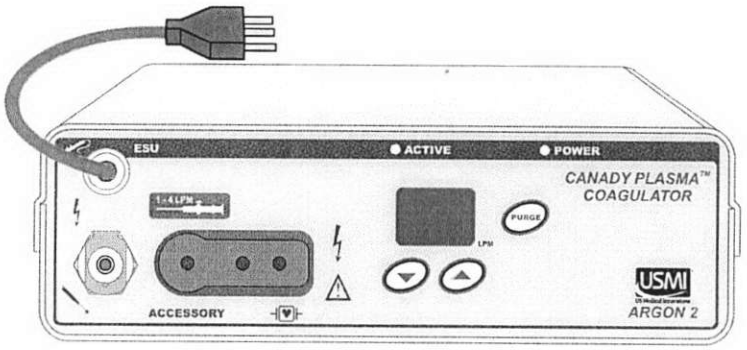
Manufactured for US Medical Innovations, LLC
WEM Equipamentos Eletrônicos Ltda.
Rua Marechal Mascarenhas de Moraes, 550
14095-120 – Ribeirão Preto – SP – Brasil

Contents

1 – IDENTIFICATION

1.1 – Name and model

Technical name: Coagulator
Commercial name: Canady Plasma™ Coagulator
Commercial model: Argon 2



1.2 – Equipment description

The Canady Plasma™ Coagulator (Argon 2) is an Arqon Plasma unit designed for Hybrid Plasma cut and gas enhanced coagulation when used only with the Canady Plasma™ Electrosurgery Unit model (SS-200E). SS-200E electrosurgery unit provides the high frequency (HF) voltage which ionizes the inert gas (Argon) from the Canady Plasma™ Coagulator (Argon 2) to form a gas stream. A communication cord connects the Canady Plasma™ Coagulator to the Canady Plasma™ Electrosurgery Unit model (SS-200E). The Canady Plasma™ Coagulator (Argon 2) is intended to provide Hybrid Plasma cutting and gas enhanced coagulation during open surgical procedures where monopolar electrosurgery (cutting and coagulation) is normally used

Indications for Use for the Canady Hybrid Plasma™ Scalpel

The Hybrid Plasma Scalpel provides enhanced cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

1.3 – Components

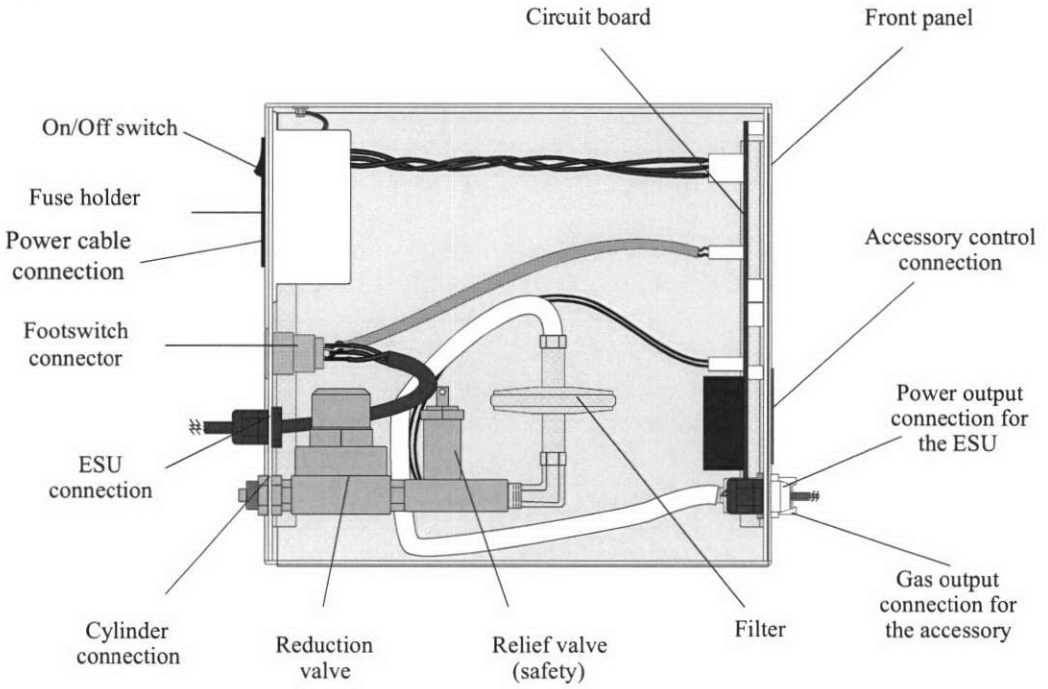


Figure 1: Internal View of Argon 2

1.4 –Physical principle and fundamentals of electrocoagulation

There are three modes of high frequency electrocoagulation: monopolar, bipolar, and fulguration. Monopolar and bipolar electrocoagulation are the two primary modes of high frequency energy used today during surgery and endoscopic therapy. Argon Plasma Coagulation is a monopolar thermoablative method of electrocoagulation that is widely used in surgery and endoscopy today. Hybrid plasma cut is a new monopolar thermoablative method of electrosurgery that cuts and coagulates the tissue at the same time.

Argon PlasmaCoagulator (APC) is an argon gas flow unit which operates coupled to an electrosurgical unit. Accessory devices (argon plasma flexible probes (catheters) or handpieces) can be attached to a high frequency electrosurgical argon plasma coagulator unit. The plasma current is activated by a footswitch or a handpiece and when the tip of the probe or handpiece is approximately 2 to 10 mm from the target tissue. The electrosurgical unit delivers a high output voltage of 5000-6500 Vpp which is delivered by a tungsten wire within the lumen of the probe (catheter) or handpiece. Argon gas flowing through the lumen of the probe or handpiece is ionized by this high voltage spark.

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1.5 – Options

a) Cylinder

Figure 2: Cylinder

b) AW-FSXX double footswitch

Figure 3: AW-FSXX double footswitch

c) CA-XX probe

Figure 4: CA-XX probe

d) Transportation unit

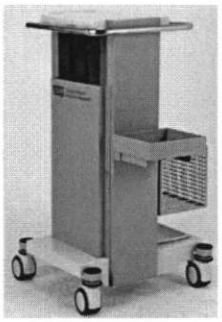

Figure 5: Transportation unit

1.6 – Consumables and supporting materials

a) Consumables
Argon gas

b) Supporting material
Operating manual

Manufactured items for exclusive use with company products
All the parts, accessories and optional parts described in this operation manual, and others non-specified, are for exclusive use with the company products.

Attention: *the User is entirely responsible for the use of any non-specified part, accessory, or material*which is not listed in this manual US Medical Innovations assumes **no liability** in the event that unauthorized accessories are used with this equipment. **The warranty shall be rendered null and void if unauthorized argon accessories (*not authorized by US Medical Innovations) are attached to the Canady Plasma™ Coagulator Argon 2 or if unauthorized repairs are made or attempted on this product.**

1.7 –Technical specifications and features

Class (MDD 93/42)	Class IIb
Class (ANVISA)	Class III
Equipment dimensions (Length x width x height)	Length: 243 mm Width: 74 mm Height: 260 mm
Area required	0,010 m^3
Packaging dimensions	0,29 X 0,37 X 0,45 m
Packaging type	Cardboard
Net weight	12 kg
Gross weight	13,3 Kg
Electric voltage supply range	100 to 240 VAC with automatic voltage selection
Main Frequency	45 / 65 Hz
Current consumption	0,09A (127 VAC) 0,08A (220 VAC)
Current type	AC (alternating)
Number of phases	Double phase
Operating voltage selector	Automatic voltage selection
Operating Mode	Intermittent operation
Protection against electric shock	Applied part Type CF Class I equipment
Protection against harmful ingress of water	Common equipment - IPX1 (Drip-proof enclosed equipment)
Rated input power	15VA
External fuses	5A / 250V
Type of fuses	Glass (model 20AG), 20 mm, quick action

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Table 1: Technical Specifications and Features

THIS EQUIPMENT IS NOT SUITABLE FOR USE IN EXPLOSION-PRONE ATMOSPHERES

Detailed dimensions of unit

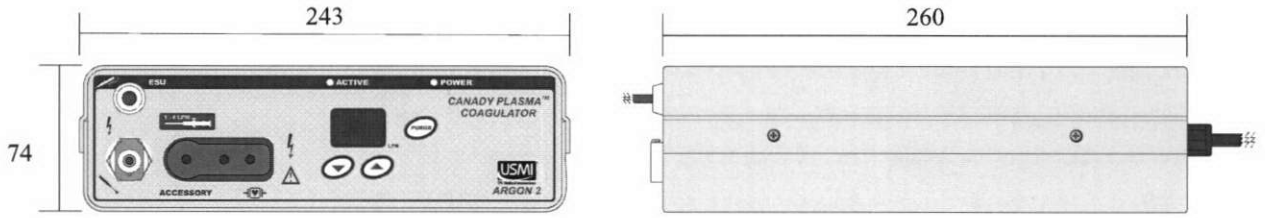


Fig: 6: Dimensions of equipment

Fuses

When fuses burn out, they must be replaced with F5A-type 250 V glass fuses.

To replace a fuse, use a screwdriver to remove the fuse holder cover located on the rear panel. Replace the burned out fuse with the spare one stored in the fuse holder cover.

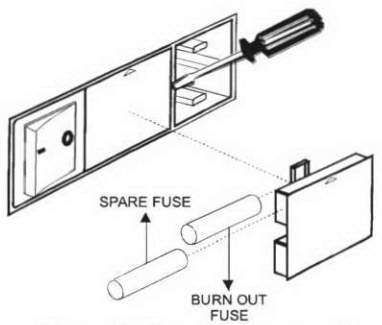


Figure 7: Fuse replacement

Standards applied to the equipment design and development

IEC 60601-1 Standard	– Electromedical equipment – Part 1 – General requirements for safety
IEC 60601-2-2	– Electromedical equipment – Part2 - 2: Particular requirements for the safety of high frequency surgical equipment
IEC 60601-1-2	– Electromedical equipment – Part 1 - 2: Collateral standard: Electromagnetic compatibility – Requirements and tests

Standards applied to the equipment manufacturing process

ISO 9001 Standard	– Quality management systems – Requirements
RDC 59 (ANVISA) Standard	– Good Manufacturing Practices for Medical Products
EN ISO 13485 Standard	– Quality systems – Medical devices – Particular requirements for the application of ISO 9001

Classification

Canady Plasma™ Coagulator, model Argon 2 has the following classifications according:

- **Operation Mode**

This equipment is classified as Intermittent Operation.

- **Protection Degree Against Electric Shock**

Type CF equipment: it has defibrillation-proof applied parts protection. This equipment is appropriate for direct cardiac application. Safety symbols are shown in section 3.4 of this manual.

- **Safety Degree**

This equipment is not adequate for use in the presence of an air-flammable anesthetic substance, oxygen or nitrous oxide (see section 4.6).This equipment does not fit the APG Category.

- **Protection Degree of Against Harmful Water Penetration**

This equipment provides protection against harmful water penetration as described by classification IPX1: equipment protected against water dripping or drip proof.
The equipment is endowed with an enclosure that protects it against the entrance of vertically dripping water, in such amount that can interfere with the satisfactory and safe operation of the equipment. Safety symbols are shown in section 3.4 of this manual

High Voltage
High voltage is present in the outlets of accessory connections and in accessories' tips with the equipment activated (see section 4.6). Safety symbols are shown in section 3.4 of this manual.

Equipment Installation
Equipment must be installed according to instructions in section 6.0 of this manual.

Equipment Operation
Equipment must be operated according to instructions in sections 1.4 (Theory and Physical Principle) and 3.5 (Equipment Operation/Preparation for Use) of this manual.

Biocompatibility
The equipment does not have parts that come into contact with the patient's body.

Accessories Substitution
Guidelines for use of accessories used with this equipment are described in section 4.8 of this manual.
Guidelines for the use of, and risks associated with the use and disposal of, accessories used with this equipment are described in section 13 of this manual.

Circuit Schematics, Part Lists, Components
See section 1.3 and 7.6 of this manual.

Mechanical Stability
The equipment is secure against overbalance, when tilted through an angle of 5°.The equipment, when placed on a transport unit, must be protected from tipping when tilted to an angle of 10°.

Protective Storage
Storage guidelines for this equipment and its accessories are described in section 2 of this manual.

Environmental Conditions for Transport and Storage
See section 2 of this manual.

Care To Be Taken When Using Argon Gas
The cylinder to be connected must contain 99.998% pure Argon gas, minimum. Argon gas is an odorless, colorless, chemically inert noble gas, found in the atmosphere. **Only commercially available ARGON 4.8 gas cylinders are to be used with the Canady Plasma™ Coagulator Model Argon 2 unit. Only the pressure regulator supplied by US Medical Innovations is to be used.**Maximum input pressure must not exceed 2900 PSI (200 BAR). **The pressure regulator supplied by US Medical Innovations is set at 160 PSI and should never be adjusted to a higher pressure**. Do not remove the safety seal on the pressure regulator. US Medical Innovations assumes no liability in the event of unauthorized used of this equipment. **Warranty guarantee shall be rendered null and void if an unauthorized pressure regulator is attached to the product or if unauthorized repairs of the pressure regulator are made or attempted on this product.** The equipment is designed to connect with one argon gas cylinder.

Argon is non- toxic. All precautions about handling and storage of argon gas must be taken.

Argon gas is non-flammable, but the cylinder in which it is stored may rupture due to fire or heat.No part of the cylinder should be subjected to temperatures above 125 °F (52 °C); however, the cylinder is fitted with a pressure-relief device.

The cylinder must always be free from any risk of falling and must always be transported in a cylinder-carrying cart. Never drag or roll the cylinder or allow it to fall. Should the cylinder begin to leak, close the valve, and with the equipment turned off, disconnect the cylinder from the Argon 2 unit. Take the cylinder to a well-ventilated area and call the gas distributor to change or repair it.

2 –SPECIAL CONDITIONS FOR EQUIPMENT STORAGE, CONSERVATION AND/OR HANDLING

Storage: Keep unit in a location protected from moisture, rain, or and direct sunlight, and store it in the original packaging.
When storing multiple boxes of packaged units, follow maximum stacking guidelines as shown on the packaging.

Conservation: When unit is in use, clean it with a moist cloth.
Keep the unit clean for the next use.
Do not allow liquids to drip into the unit.
Do not use organic solvents, such as thinner, to clean the unit.
Keep the unit in a clean, dust-free environment.

Transport: Transport the unit in its original packaging. Avoid subjecting the unit to vibration or impact.
Do not drop the unit.

Symbols printed on the packaging related to storage and transportation

	Position of packaging for storage and transportation		Maximum stacking load permitted
	Maximum stacking		Temperature limits
	Protect against water		Humidity limits
	Fragile contents		

Table 2: Symbols printed on the packaging

Environmental conditions
Room temperature –40°C to 70°C (–40°F to 158°F)
Relative humidity: 10% to 100%
Atmospheric pressure: 500hPa to 1060 hPa (375 mmHg to 795 mmHg)

3 – INSTRUCTIONS FOR USE OF THE EQUIPMENT

Attention: This equipment must be used only by qualified medically trained personnel.

3.1 – Operating conditions

The operating and storage conditions of the equipment conform with General IEC 60601-1 Standard (Section 2 – Environmental conditions).

Room temperature range from +10 °C to +40 °C
Relative humidity range from 30 % to 75 %
Atmospheric pressure range from 700 hPa to 1060 hPa (525 mmHg to 795 mmHg)

3.2 – Front Panel Controls, Indicators and Connections

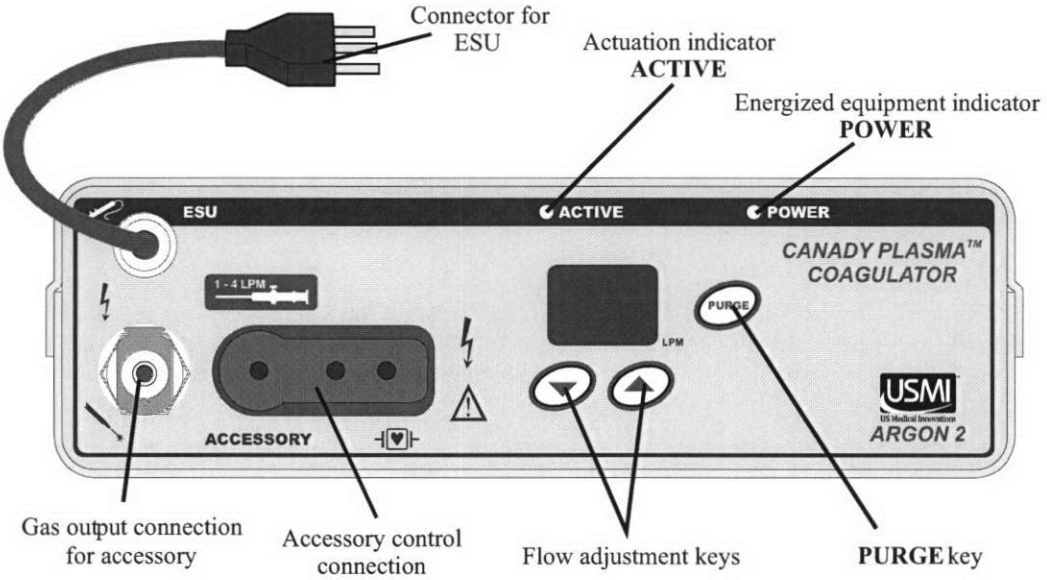


Figure 8: Front panel

3.3 –Rear Panel Controls, Indicators and Connections

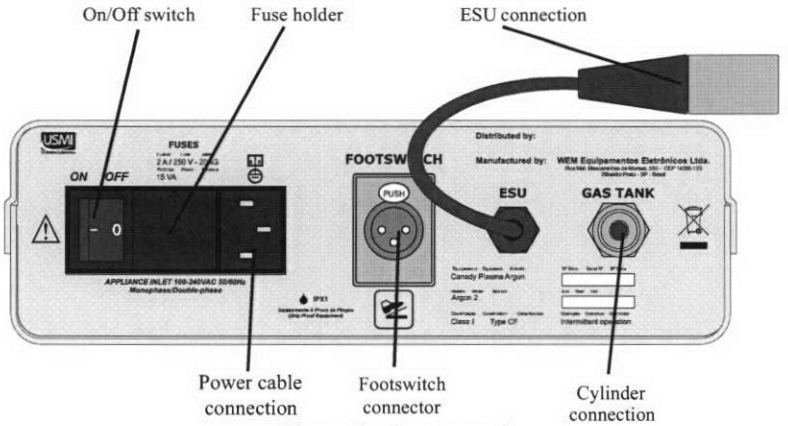


Figure 9: Rear panel

3.4 –Other symbols used on the equipment

Front Panel


Before using the Argon 2, please refer to the accompanying documentation


Purge control


Indicator of argon coagulation activated


High-voltage output


Electrosurgical unit connection


Connector for ES-XX handpiece, CA-XX catheter, etc.


Indicated flow for laparoscopic procedures.

Rear Panel


Connect the Argon 2 to grounded electric main


Footswitch connector

SN Serial Number

Accessories


Manufacturing Date


Validity


Disposable

Table 3: Symbols used on the equipment

3.5 –Operating the equipment
Once the equipment is properly installed, according to section 6, follow the instructions below:

1. Set the **ON/OFF SWITCH**located on the rear panel of the Argon 2 unit to**OFF**. Set the **ON/OFF SWITCH** of the electrosurgical unit (ESU) switch to **OFF**.
2. Connect the power cord supplied with the Argon 2 into the rear panel power cord connection. Do the same with the ESU, if its cord is detachable.
3. Open the gas valve (see section 7.6).
4. Connect the Argon 2 and the ESU power plugs to grounded outlets (see sections 7.3, 7.4, and 7.5).
5. Connect the ESU connector to the ESU power output (for further information, refer to the manufacturer manual and/or see more details in section 6).
6. Set the **ON/OFF SWITCH** of the Argon 2 unit to **ON** position.
7. Set the **ON/OFF SWITCH** of the ESU to **ON**. If the ESU has a **STAND-BY** mode, set it to the operating mode for Monopolar/Coagulation for fulguration (SPRAY).
8. Set the gas flow rate using the increase and decrease controls located on the Argon 2 front panel.

3.6 –Gas purge
1. To purge air from the gas lines, press the **PURGE** button (located on Argon 2 front panel) for approximately 10 seconds.Purging is necessary to expel the air in the gas lines and replace it with argon gas. The **PURGE** procedure will not activate the ESU.
2. Purge the gas lines by pressing the **PURGE** button before starting surgery or whenever an accessory is replaced.
3. Set the flow rate to the desired levels, according to ESU power levels or to the surgeon's preference.

3.7 – Reconnected cylinder (new or reinstalled cylinder)
A zero (0) reading on the manometer that is connected to the cylinder indicates that the cylinder valve is closed. If this is the case, open the valve. If manometer continues to indicate zero (0), change the cylinder gas.

Before replacing the cylinder (refer to section 7.6 for information about replacing the cylinder) or after a cylinder is connected, press the **PURGE** button on Argon 2 front panel. (The **PURGE** procedure will not activate the ESU.) Set the gas flow rate to the desired levels, according to the ESU power levels or to the surgeon's preference.

3.8 –Starting coagulation with Canady Plasma™Coagulator
The Argon 2 and the ESU must be installed according to the guidelines in sections 6.0.To perform coagulation with argon gas, press the **COAG** lever on the footswitch or BLUE button on the hand piece. If the indicator light for argon plasma coagulation is not activated after pressing on the **COAG** lever on the the footswitch or hand piece, check the manometer connected to the gas cyclinder. A zero (0) reading indicates on the manometer that the cylinder valve is closed or cylinder is empty. The probe or handpiece cannot initiate a plasma beam if there is no gas flow.

CANADY PLASMA™ BEAM INITIATION. Because beam initiation depends on several variables, such as ESU output voltage, tissue type and/or probe or accessory type, start the argon gas beam by holding the tip one centimeter (1/2 inch) from the patient's tissue. Once the beam is initiated, the tip of the hand device may be positioned at a certain distance from the target tissue to provide a more comfortable position and to obtain the desired beam. An angle of 45° to 60° between the probe and the tissue surface is recommended to obtain optimum performance. Note that the tip will glow if it is too close to the tissue or if the ESU power is excessively high. The tip of the probe must be within 1 cm (1/2 inch) from the tissue surface for sparking to begin.

3.9 –Activation of the Canady Vieira Hybrid Plasma™ Scalpel.

The handpiece consists of three major components: Handle, Telecscoping Nozzle, and Electrode. The insulated handle encases the high frequency(HF) current and gas tubing for controlling the flow of argon gas and activation of HF current for the device. HF current is activated by two push buttons yellow (standard **CUT** mode) and blue (standard **COAG** mode) which are on top of the handle. Argon gas is delivered via the handle by activating a third push button (purple) which is also on top of the handle. Depending on the RF current mode (**CUT** or **COAG**), the handpiece can function in the following plasma modes: **HYBRID PLASMACUT** – First push the purple button to activate the gas delivery afterwards press down on the yellow button to start Hybrid Plasma Cut. Hybrid Plasma Cut mode will cut and coagulate the tissue at the same time. To switch back to standard cut mode press down on the purple button afterwards press down on the yellow button to cut.**ARGON PLASMA COAGULATION (APC)** – First push the purple button to activate the gas delivery afterwards press down on the blue button to start Argon Plasma Coagulation.To switch back to standard **COAG** mode press down on the purple button afterwards press down on the blue button to start coagulation. Canady Plasma™ Argon 4 provides a controlled flow of argon to the electrosurgical handpiece during Hybrid Plasma Cutting or Argon Plasma Coagulation modes. The physician manually sets the flow rate on the plasma coagulator and power (watts) on the electrosurgical generator. The telescoping nozzle can be extended or shortened over the electrode as desired when the surgeon is performing plasma procedures. The electrode tip delivers RF energy for standard **CUT, COAG, ARGON PLASMA COAG** and **CANADY VIEIRA HYBRID PLASMA™ CUT**.

IMPORTANT: Do not point the tip at open vessels. Do not try to coagulate vessels larger than 3 mm in diameter.

4 – WARNINGS AND/OR PRECAUTIONS TO BE TAKEN

4.1 – Warnings and/or precautions during transportation and storage

During transportation (packaged product), avoid vibration and impact to the unit.

Do not leave the unit exposed to rain or to excessive moisture. Avoid dropping the packaged unit.

When the unit is not to be used for a prolonged period of time, unplug the unit from the electric outlet and close the cylinder.

Cylinder must be well fastened to transportation unit. Never roll the cylinder; protect it from falls, excessive heat or fire.

4.2 – Warnings and/or precautions during installation

Do not install the unit near water faucets or similar devices. Do not install the equipment close to abnormal atmospheric pressure or temperature, high moisture, intense sunlight, poor ventilation, alkaline or acid environment, dust, chlorine, or sulfuric acid.

Make sure the unit is only installed in a stable location. Make sure the unit is in a safe place in terms of tilting, vibration, or shocks.

Check whether the unit voltage and frequency match those of the local electrical supply. If necessary, the unit must be switched to the same rating as that of the local electric supply.Check whether the supply lines where the unit is to be connected are properly grounded.

For safety reasons, disconnect the unit from the main electrical supply during installation.

Check whether the cylinder is in the correct position and well fastened to the equipment transportation unit and that there are no leaks at the connections.

4.3 – Warnings and/or precautions during use

Do not attempt to repair the unit. Call the US Medical Innovation's authorized technical representative. Note: US Medical Innovations assumes **no liability** in the event that unauthorized accessories are used with this equipment. **The warranty shall be rendered null and void if unauthorized accessories (*not authorized by US Medical Innovations) are attached to the Microprocessed Canady Plasma Coagulator Argon 2 or if unauthorized repairs are made or attempted on this product.**

Never unplug the equipment by pulling on the output power cable. Disconnect the plug from the outlet.

Attention: This equipment must be used only by qualified medically trained personnel.

4.4 –Warnings, recommendations and care during surgical procedures

Check all the accessories and connections to the Argon 2 unit before starting to work. Make sure all accessories are working properly. Faulty connections may produce metal-to-metal sparking, thus resulting in neuromuscular stimulation to the patient, accessory malfunction, and/or undesirable surgical effects.

Caution should be employed when electrosurgery is used on patients with internal or external pacemakers. The interference produced by the electrosurgery current may cause improper functioning of the pacemaker. A cardiologist or the pacemaker manufacturer must be consulted in such cases.

To avoid burns due to current deviations, make sure that the patient does not come into direct contact with grounded metallic objects (surgery table, instrumentation tables, etc.) during the procedure. When this is not possible, the use of antistatic sheeting is recommended to assure the patient's safety.

Contact between the patient's body parts may result in burns due to the circulation of current between these parts. Dry gauze must be used in order to separate them.

To avoid interruptions caused by a unit fault or malfunction, a spare unit should be kept in proper conditions to be utilized instead.

Special care must be taken when using electrosurgery very near or in direct contact with metallic objects such as forceps, specula, clamps, etc. The use of electrosurgery in these conditions may cause tissue destruction and unintentional burns.

Use the minimum power lever required for the surgical procedure in question. In general, starting with a low power level and gradually increasing power yields the best result. Avoid increasing the power level without first checking to ensure that connections are in good condition. Use the active electrode as little as possible to obtain the desired surgical effect while reducing the possibility of burns.

The cables of the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided.

Sparking and heat generation associated with electrosurgery may constitute an ignition source for flammable materials such as:

- Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen, if a surgical procedure is carried out in the chest or the head, unless these agents are sucked away.
- Accumulation of flammable solutions under the patient or in body depressions or cavities such as the belly button or the vagina. Any fluid accumulated in these areas should be removed before the equipment is used.
- Endogenous gases.
- Hydrophilic cotton or gauze saturated with oxygen.
- Flammable substances such as alcohol-based dyes used in preparing the patient for surgery.
- Flammable natural gases which may accumulate in cavities, such as the bowel.
- Adhesive products such as flammable solvents.

Whenever possible, use non-flammable agents for cleaning and decontamination. Otherwise, wait until the flammable agents used for cleaning or disinfecting evaporate before performing high-frequency surgery.

The equipment operates at dangerous voltage levels. Only qualified personnel must use this equipment.

This equipment produces physiological effects.

This equipment produces interference that may adversely influence the operation of other electronic equipment.

Failure of this equipment could result in an undesired increase in output power.

Never use for endometrial ablation. High risk of air/gas embolism inside the uterus. Do not aim the jet into open vessels.

Use it with care near delicate tissues such as the intestine, bladder, ureter, major vessels.

4.5 – Caution during endoscopic and laparoscopic procedures
If the electrosurgical unit is unintentionally activated or moved out of visual range while activated, patient injury may result. Continually monitor intra-abdominal pressure during activation of Argon 2; do not allow it to exceed 15 mmHg.

4.6 –Care with accessories
Before each use, check each accessory (hand piece, clamp, etc.) and observe its condition (overheating, cracking, failures, broken cables, broken connector, etc.). Repair or replace accessories in order to avoid safety risks to the patient as well as to the operating team.

Discard adhesive plates after use.

Do not wrap the patient plate or accessory cables around metallic objects. Doing so may induce potentially dangerous currents in these objects, which may cause shock and burns to the patient or to the operating team.

Do not connect wet or internally damp accessories to the unit. There may be a risk of electric shock.

Whenever more than one accessory is connected to the unit (for instance, a manually-controlled hand piece and two footswitch-controlled hand pieces), keep the accessories that are not being used in a safe place, such as in a plastic or fabric bag that can be attached to the surgery field. Doing so reduces the risk of burns.

An apparently low output power or failure in equipment operation under normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections (see Proper Plate Use – section 7.7).

Accessories connected to the unit must withstand at least the maximum peak output voltage of the intended operating mode and power settings (see charts in section 1.7).

4.7 – Warnings and/or precautions during cleaning
Prior to cleaning the unit, verify that it is switched off.

For external cleaning of the unit, use a damp cloth. Be careful not to allow any liquid to enter the equipment. If liquid is spilled into the unit, do not turn the equipment on. Call the Authorized Service Dealer immediately.

Do not use microabrasive material or stainless steel sponges to clean the unit. Do not use organic solvents or detergents containing solvents such as ether, stain remover, gasoline, etc. Do not use aerosols or liquid spray dispensers.

5 – ESSENTIAL SAFETY REQUIREMENTS, EFFECTIVENESS OF MEDICAL DEVICE, POSSIBLE UNDESIRABLE SIDE EFFECTS

5.1 – Recommended use and purpose

Recommended use: Cutting or coagulation of biological tissues
Purpose: Hybrid Plasma cutting and enhanced coagulation of biological tissues through the use of argon gas

5.2 – Undesirable secondary or side effects.

The unit does not produce any undesirable secondary or side effects if all recommendations in this operating manual are followed. The unit may only be used or operated by qualified professionals (physicians) or under their supervision.

5.3 – Equipment safety and effectiveness:

The equipment is safe if the operating manual instructions are followed.

6.0– INSTALLATION OR CONNECTION TO OTHER EQUIPMENT

The Canady Plasma™ Coagulator Argon 2 must beonly used with a US Medical InnovationsSS-200EElectrosurgery Unit (ESU) that has "Spray" mode of coagulation with a minimum voltage of 5000Vpp and in accordance with the electrical safety guidelines IEC 60601-1 and IEC 60601-2-2.

The Canady Plasma™ Coagulator Argon 2 is provided with a transport unit that allows different US Medical Innovations ESUs to be placed at the rear part of the top of the module.

The bottom of the ESU bottom must be inserted in the grooves on the top of the Argon 2 unit to avoid accidental displacements of the ESU. These 4 grooves were especially designed to house the US Medical Innovations' *SS-200E* unit.

To install the Canady Plasma™ Coagulator Argon 2 unit:
1. Make sure the Argon 2 and the ESU are disconnected from the power supply.
2. Connect the Argon 2 front panel connector to the output for pencil grip with footswitch control of the ESU.
3. Connect the footswitch to the Argon 2 back panel.
4: Connect the accessory to the output on Argon 2 font panel.

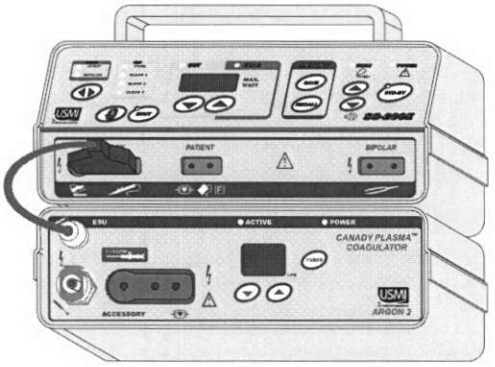


Figure 10: Installation of electrosurgical unit and accessories

Note: *The user is entirely responsible for the use of any non-specified part, accessory, or material.* US Medical Innovations assumes **no liability** in the event that unauthorized accessories are used with this equipment. The warranty shall be rendered null and void if unauthorized accessories (*not authorized by US Medical Innovations) are attached to the Canady Plasma™ Coagulator Argon 2 or if unauthorized repairs are made or attempted on this product.

7 – INSTALLATION AND CORRECTIVE AND PREVENTIVE MAINTENANCE

7.1 – Equipment installation

After unpacking the unit, make sure there is no apparent damage caused by shock or improper handling during transportation. If such damage is apparent, contact the transportation company immediately for information on procedures to follow.

US Medical Innovations is held responsible for the safety, reliability and performance of the equipment as long as:

1. *the equipment is used according to the operating instructions contained in this manual.*
2. *the electric wiring is in accordance with the International and United States regulations in force for hospital facilities.*

7.2 –Use with the transport unit

The transport unit is an included accessory. Hold onto any equipment already attached to the unit when transporting it on uneven surfaces. After the unit is positioned in place and in use, avoid moving it so as not to disconnect the electrode cables or the power supply cord.

7.3 –Power plug

The power cord plug supplied with the equipment is of the 3-pin type: 2 flat and 1 round hospital grade NEMA 5-15P, IEC 320 / C13 Connector. The round pin must be connected to the ground The ground pin must be connected to ground. Contact the manufacturer for an alternate cord and plug if the surgical center wiring installation does not permit use of the supplied cord and plug. Note that the wiring installation must meet the requirements specified in this manual (NEMA 3P or other type).***Extension cords or three-to-two pin adapters without grounding pin must not be used***. Regular inspections of the power cord must be carried out in order to check for damage to the plug or cord. When unplugging the equipment, always pull by the plug and never by the cord.

7.4 –Grounding

In order to ensure patient as well as surgeon safety, the Argon 2 must be properly grounded.The ground wire in the power cord is connected to the equipment frame, thus preventing the circulation of dangerous currents coming from the equipment box in case of a power failure.If the site where the equipment will be utilized is not fitted with adequate ground, proper ground connections must be provided before the unit is switched on.

7.5 –Main voltage

The Argon 2 can be connected to any power outlet whose voltage rating is between 100 VAC and 240 VAC. In case of doubt, check with qualified personnel. Check whether the fuse complies with the specification printed on the rear panel of the equipment, in accordance with sections 1.6 and 7.7.

7.6 –Cylinder installation

The cylinders used with the unit must contain Argon Gas of 99.998% minimum purity. The maximum input pressure should not exceed 2900PSI (200BAR). The equipment is designed to connect to one argon gas cylinder.

1: Place the argon gas cylinder on the transport unit base.
2: Connect the gas hose to the Argon 2 connection and tighten the connection by hand.
3: Align the cylinder groove with the gas connector hose.
4: Affix the cylinder to the cart using the clamp attached to the cart.
5: Connect the hose to the cylinder and tighten the connection by hand.
6: Open the gas valve. A brief shrill sound will be heard when the valve is opened. If this shrill sound lasts more than 2 seconds, close the valve immediately and look for incomplete and/or misaligned connections. If the problem persists, contact US Medical Innovations Technical Assistance.

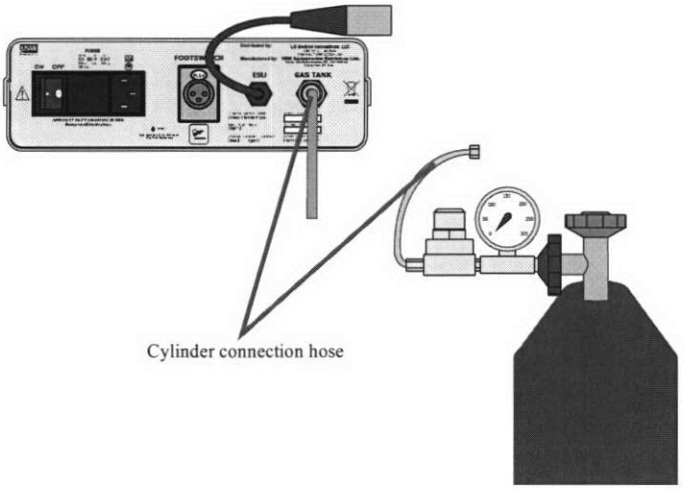


Figure 11: Installation of Cylinder

7.7 – Corrective maintenance and repairs

During the warranty period, corrective maintenance shall be directly carried out by the manufacturer or by any other authorized technical dealer. If not, the warranty will be voided, unless the client is given written authorization by US Medical Innovations to proceed otherwise. In this case, the factory will supply the necessary information and spare parts.

PROBLEM	SOLUTION
Unit will not switch on	- Ensure that the power cable is connected to the main electrical supply. - Ensure that the outlet has electric power. - Ensure that the power cable is not broken. - Ensure that the switch is not damaged. - Check the fuses on the rear panel; if any are blown, replace them (with the equipment switched off).
Gas leakage	- Internal leak in equipment. Turn the equipment off and on; if the "gas leakage" message persists, contact US Medical Innovations Technical Service.
Unit **blows fuses**	- Ensure that the fuse amperage matches that of the indicator. - Ensure that cabling or any connections have not shorted out.
Equipment has no power output	- Ensure that the footswitch is properly connected. - Ensure that the 3-prong connector is properly connected to the generator output. - Ensure that the accessory (handpiece, catheter, etc.) is properly connected to the Argon 2 output. - Ensure that the accessory is in good condition. - Ensure that there is pressure in the cylinder>Ensure that the output flow has not been improperly adjusted. Open the cylinder valve or adjust the output flow. - Ensure that the generator is switched on. - Ensure that the generator is not in standby status and that its power level is properly adjusted.
Plate circuit fault alarm activated (intermittent visual and sound alarm)	- Ensure that the plate cable is properly connected to the plate and to the generator. - Replace the plate cable.
Neuromuscular stimulation	- Stop the surgery. - Check all accessory connections and make sure there is no faulty contact. - Lower power levels to reduce neuromuscular stimulation. - Fulguration tends to produce more neuromuscular stimulation than cutting due to the higher voltage levels involved.Desiccation should not produce neuromuscular stimulation because there is no sparking involved.

Interference with the heart monitor	- Ensure that the power cord ground wire is not broken. - Check the integrity of the frame-grounding connection for the electrosurgery unit and for the monitor. - Ensure that the electric wiring grounding circuit in the surgery room is adequate. - Check the plate cable and accessory connections. Metal-to-metal sparking resulting from faulty connection may cause interference. - Fulguration tends to produce a higher level of interference than cutting. Lower power levels produce less interference.
Interference with pacemakers	- Check the plate cable and accessory connections. Metal-to-metal sparking resulting from faulty connection may cause interference. - Use bipolar instruments. - When using monopolar instruments, place the patient plate as close as possible to the surgery area and keep the path traveled by the current as far away as possible from the heart muscle.

Table 4: Corrective maintenance

Note:*If the problem cannot be solved with the solutions given above, request the Authorized Dealer Service through US Medical Innovations Customer Service Department at 863 667-1609, fax 863 667-1917, or refer to the List of Authorized Dealer Services that comes with the equipment.*

Electro-electronic diagrams, parts list, and technical information.
The electro-electronic diagrams, parts lists and any other necessary information may be provided by US Medical Innovations, LLC, provided they are necessary for the technical upkeep of the equipment by the user, after mutual agreement between the parties.

Warranty Conditions

WARRANTY
The warranty is limited to replacement and/or repair of any defective parts or the correction of any manufacturing defect, upon verification by our Technical Service Department.

The replacement and/or repair referred to in the previous item does not apply to worn parts due to regular use (fuses, etc.), as well as failure due to misuse or negligence when using the equipment, or else to parts that have been repaired or modified by personnel not authorized by US Medical Innovations.

Original warranty shall not be extended due to replaced component.

EQUIPMENT
This warranty is valid for all US Medical Innovations brand equipment manufactured by US Medical Innovations, LLC

INSTALLATION AND USE
The installation and/or operation of the equipment as well as working conditions under which it is operated must comply with the US Medical Innovations rules contained in this Operating Manual. Under conditions different from those indicated, **the warranty shall be null and void.**

WARRANTY LOCATION
The US Medical Innovations-certified Authorized Technical Service shall be carried out by a US Medical Innovations technician and be limited to repair and/or replacement of the parts.

Whenever it is found that a repair of the equipment can only be completed at our facilities (factory) or by the technical representative authorized by us, the transportation cost (both ways) shall be borne by the purchaser.

WARRANTY PERIOD

Warranty begins on the date when the product is delivered to and accepted by the purchaser. The warranty is valid for 24 months.

RESPONSIBILITY
This warranty is valid only for the equipment that is under use and possession of the original purchaser.

US Medical Innovations' responsibility is limited to replacing and/or repairing the components, with possible losses due to lost profits or indemnification for any other indirect or immediate damages being excluded from the warranty.

Request the Authorized Dealer Service through US Medical Innovations Customer Service Department at 863 667-1609, fax 863 667-1917, or refer to the List of Authorized Dealer Services that comes with the equipment.

7.8 –Preventive maintenance

On a daily basis, check:
- If there is oxidation on the power cords
- If uncommon odors occur when the equipment is switched on
- If there is no physical damage to the equipment housing

On a weekly basis, check:
- The conditions of the power source (main electric outlet)
- If there are leaky cylinder connections

On a annual basis:
Preventive maintenance inspection is recommended on an annual basis. During that annual preventive maintenance check, replacement of the high-efficiency internal filter is recommended, due to impurities or particles that may be found in low-quality argon gas cylinder.

The filter is designed to retain impurities or particles, and must be changed every year to ensure argon gas purity and to improve equipment efficiency. Preventive maintenance must be performed by US Medical Innovations or one of its Authorized Service Dealers.

8 – ADDITIONAL PROCEDURES FOR REUTILIZATION

Cleaning and Sterilization Methods
A. *Cleaning with water and neutral soap*

* Sterilization with germicides such as Glutaraldehyde (pentanedial) is not recommended because the substance is extremely corrosive and may damage stainless steel and silicon parts.

Storage
Keep unit away from rain or excessive moisture. When the unit is not to be used for a prolonged period of time, unplug the unit from the electric outlet.

9 – ADDITIONAL PROCEDURES BEFORE USING THE EQUIPMENT
Even before its first use, the unit must be cleaned, following the same procedures as described in section 8 of the operating manual.

10 – PRECAUTIONS IN CASE OF ALTERATION IN EQUIPMENT OPERATION
Should the unit make any abnormal noise or produce excessive heat, stop using the unit immediately. Check the troubleshooting guidelines in section 7.7. If the problem cannot be solved, switch the unit off, remove the power cord from the electric outlet and call technical service through the US Medical Innovations Customer Service Department at 863 667-1609, fax 863 667-1917.

11 – Electromagnetic compatibility

Guidelines ad manufacturer's certificate – electromagnetic emission		
The Argon 2 argon plasma coagulator is designed for use in electromagnetic environments such as described below. The user must make sure these conditions apply.		
Emission test	**Conformity**	**Electromagnetic environment - guide**
RF emissions IEC CISPR 11	Group 1	The Argon 2 argon plasma coagulator uses only RF energy for its internal functions. However, its RF emissions are very low and they are unlikely to cause interference with nearby electronic equipment.
RF emissions IEC CISPR 11	Class A	The Argon 2 argon plasma coagulator is suitable for use in all non-residential areas and those that are directly connected to the low voltage public mains that feed residential buildings.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions due to fluctuations in sparking discharges IEC 6100-3-3	Conform	

Table 5: Electromagnetic emission

Guidelines ad manufacturer's certificate – electromagnetic emission			
The Argon 2 argon plasma coagulator is designed for use in electromagnetic environments such as described below. The user must make sure these conditions apply.			
Immunity test	**IEC 60601 test level**	**Conformity level**	**Electromagnetic environment - guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV per contact ± 8 kV through the air	± 6 kV per contact ± 8 kV through the air	Wooden, concrete or ceramic tile floors. If floors are covered with synthetic material, relative humidity must be at least 30%.
Electrical fast transient/burst immunity IEC 61000-4-4	± 2 kV in feed lines ± 1 kV in input/output lines	± 2 kV in feed lines ± 1 kV in input/output lines	The quality of power supply must be typical of hospital or commercial facilities.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of power supply must be typical of hospital or commercial facilities.
Voltage drops, short interruptions and voltage fluctuation in feed input lines IEC 61000-4-11	< 5% U_T (> 95% voltage drop at U_T) per 0.5 cycle. 40% U_T (60% of voltage drop at U_T) per 5 cycles. 70% U_T (30% of voltage drop at U_T) per 25 cycles. < 5% U_T (> 95% of voltage drop at U_T) per 5 seconds.	< 5% U_T (> 95% voltage drop at U_T) per 0.5 cycle. 40% U_T (60% of voltage drop at U_T) per 5 cycles. 70% U_T (30% of voltage drop at U_T) per 25 cycles. < 5% U_T (> 95% of voltage drop at U_T) per 5 seconds.	The quality of power supply should be typical of hospital or commercial facilities. If the equipment user requires continual operation during power cuts, it is recommended that the equipment should be fed by uninterrupted power supply or batteries.
Magnetic field at feed frequency (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at feed frequency should be typical of hospital or commercial environments.
NOTE: U_T is the AC feed voltage before the application of test level			

Table 6: Electromagnetic emission #2

Manufacturer's guidelines and certificate - electromagnetic immunity			
The Argon 2 argon plasma coagulator is designed for use in electromagnetic environments such as described below. The user must make sure these conditions apply.			
Immunity test	**IEC 60601 test level**	**Conformity level**	**Electromagnetic environment - guidelines**
IEC 61000-4-6 Conducted RF IEC 61000-4-3 Radiated RF	3 Vrms 150 KHz to 80 MHz 3 Vrms 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable or mobile RF communication device should not be used near any part of the equipment, including cables, and the minimum recommended separation, calculated according to this equation, applicable to the transmitter's frequency... Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the transmitter's maximum nominal output power in Watts (W), according to the manufacturer, and d is the recommended separation distance in meters (m). It is advisable that the field intensity produced by the RF transmitter, as determined through local electromagnetic inspection, [a] be lower than the conformity level for each frequency band.[b] Interference may occur in the vicinity of equipment marked with this symbol: 
NOTE 1: For 80MHz and 800MHz, the higher frequency band should be used. NOTE 2: These guidelines may not apply to all situations. The electromagnetic propagation is affected by absorption and reflection by structures, objects and people.			
[a] The intensity of the field produced by fixed transmitters, such as basal radio stations, telephone (cell phones and cordless) and mobile land radios, ham radios, AM and FM radio transmission and TV transmission cannot be theoretically forecast with much precision. To assess electromagnetic environments due to fixed RF transmitters, it is advisable to inspect sites for electromagnetism. If the field intensity at the site where the equipment is to be used exceeds the conformity levels above, the equipment must be inspected to verify if it is functioning normally. If abnormal operation is observed, additional procedures may be required, such as reorientation or relocation. [b] Above the frequency band of 150KHz to 80MHz, the intensity of the field is supposed to be lower than 3V/m.			

Table 7: Electromagnetic immunity

Recommended separation distances between portable or mobile RF communication devices and the Argon 2 argon plasma coagulator

The Argon 2 argon plasma coagulator is suitable for use in electromagnetic environments in which RF radiated perturbations are controlled. The user can help prevent electromagnetic interference by keeping the recommended minimum distance between portable or mobile RF communication devices (transmitters) and the equipment, as prescribed below, according to the maximum power of such devices

Transmitter's maximum nominal output power W	**Separation distance according to the transmitter's frequency m**		
	150KHz to 80MHz $d = 1{,}2\sqrt{P}$	80MHz to 800MHz $d = 1{,}2\sqrt{P}$	800MHz to 2,5GHz $d = 2{,}3\sqrt{P}$
0,02	0,17	0,17	0,33
0,2	0,54	0,54	1,03
2	1,7	1,7	3,3
20	5,4	5,4	10,3
200	16,9	16,9	32,5

For transmitters with unlisted maximum nominal output power, the separation distance d in meters (m) can be established through the equation that is applicable to the transmitter's frequency, where P is the transmitter's maximum nominal output power in Watts (W) according to the manufacturer.
NOTE 1: For 80MHz and 800MHz, the higher frequency band should be used.
NOTE 2: These guidelines may not apply to all situations. The electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

Table 8: Recommended separation distances

12 – SENSITIVITY TO FORESEEABLE ENVIRONMENTAL CONDITIONS UNDER NORMAL WORKING CONDITIONS

The Canady Plasma™ Coagulator model Argon 2 was designed to not be sensitive to interferences such as magnetic fields, external electric influences, electrostatic discharges, or pressure variation, provided the equipment is installed, maintained, cleaned, stored, transported and operated according to this operating manual.

13 – PRECAUTIONS IN CASE OF EQUIPMENT DISPOSAL

At the end of its useful life, the equipment and accessories should be disposed of properly. US Medical Innovations, LLC is not responsible for improper disposable of equipment and accessories.

Improper use after extended life time of the equipment can result in faulty operation of the equipment and accessories attached to the equipment can cause injury to the patient and user.

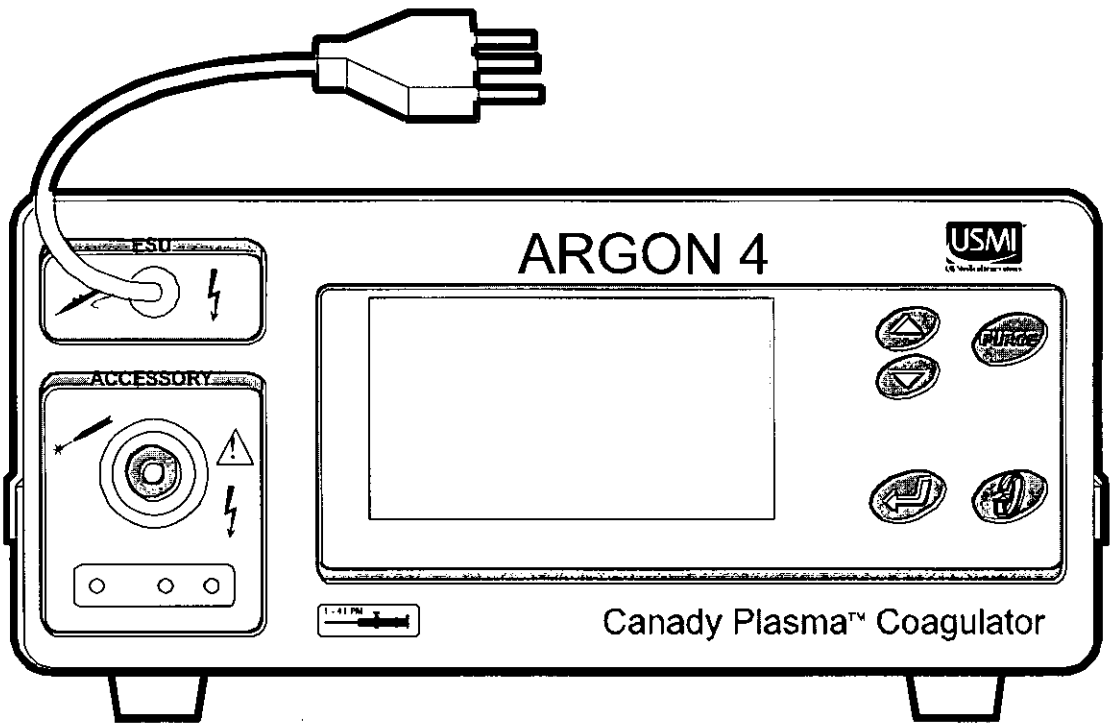
14 – LIST OF FIGURES AND TABLES

Figures and tables used in this manual.

CANADY PLASMA™ COAGULATOR

Model ARGON 4

OPERATION MANUAL



US Medical Innovations

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OPERATION MANUAL

Foreword

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the Canady Plasma™ Coagulator model Argon 4. Additional technical information is available in the service manual of Canady Plasma™ Coagulator model Argon 4.

Precaution:

Federal (USA) law restricts this device to sale, distribution or use by or on the order of a physician.

Equipment covered in this manual:

Canady Plasma™ Coagulator – Model ARGON 4 is distributed by US Medical Innovations, LLC.

Nominal Supply Voltage
100 to 240 VAC with automatic voltage selection 45 / 65 Hz

Trademark acknowledgements:
USMI Logo is the trademark of US Medical Innovations, LLC

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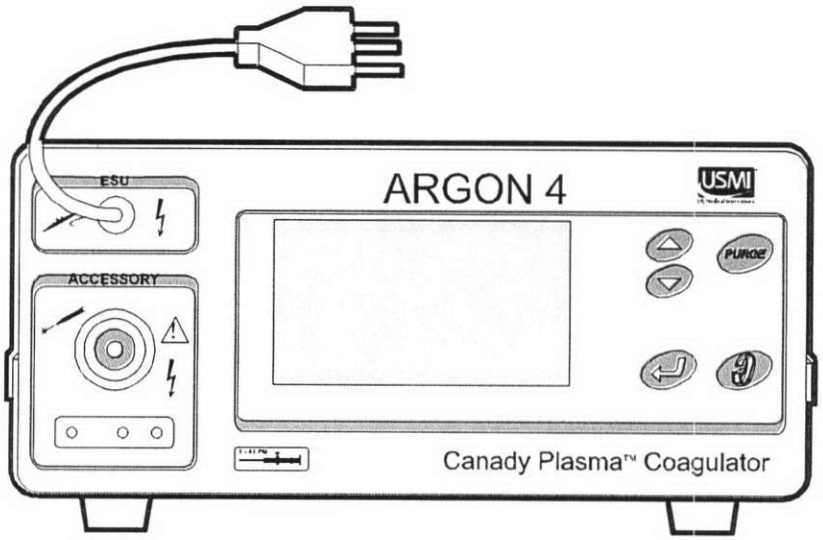
Manufactured for US Medical Innovations, LLC
WEM Equipamentos Eletrônicos Ltda.
Rua Marechal Mascarenhas de Moraes, 550
14095-120 – Ribeirão Preto – SP – Brasil

Contents

1 – IDENTIFICATION



1.1 – Name and model

Technical name: Coagulator
Commercial name: Canady Plasma™ Coagulator
Commercial model: Argon 4

1.2 – Equipment description

The Canady Plasma™ Coagulator (Argon 4) is an Arqon Plasma unit designed for Hybrid Plasma cut and gas enhanced coagulation when used only with the Canady Plasma™ Electrosurgery Unit model (SS-601 MCa). SS-601 MCa electrosurgery unit provides the high frequency (HF) voltage which ionizes the inert gas (Argon) from the Canady Plasma™ Coagulator (Argon 4) to form a gas stream. A communication cord connects the Canady Plasma™ Coagulator to the Canady Plasma™ Electrosurgery Unit model (SS-601MCa). The Canady Plasma™ Coagulator (Argon 4) is intended to provide Hybrid Plasma cutting and gas enhanced coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.

Indications for Use for the Canady Hybrid Plasma™ Scalpel
The Hybrid Plasma Scalpel provides enhanced cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

1.3 – Physical principle and fundamentals of electrocoagulation

There are three modes of high frequency electrocoagulation: monopolar, bipolar, and fulguration. Monopolar and bipolar electrocoagulation are the two primary modes of high frequency energy used today during surgery and endoscopic therapy. Argon Plasma Coagulation is a monopolar thermoablative method of electrocoagulation that is widely used in surgery and endoscopy today. Hybrid plasma cut is a new monopolar thermoablative method of electrosurgery that cuts and coagulates the tissue at the same time.

Argon Plasma Coagulator (APC) is an argon gas flow unit which operates coupled to an electrosurgical unit. Accessory devices (argon plasma flexible probes (catheters) or handpieces) can be attached to a high frequency electrosurgical/argon plasma coagulator unit. The plasma current is activated only by a footswitch or a handpiece and when the tip of the probe or handpiece is approximately 2 to 10 mm from the target tissue. The electrosurgical unit delivers a high output voltage of 5000-6500 Vpp which is delivered by a tungsten wire within the lumen of the probe (catheter) or handpiece. Argon gas flowing through the lumen of the probe or handpiece is ionized by this high voltage spark.

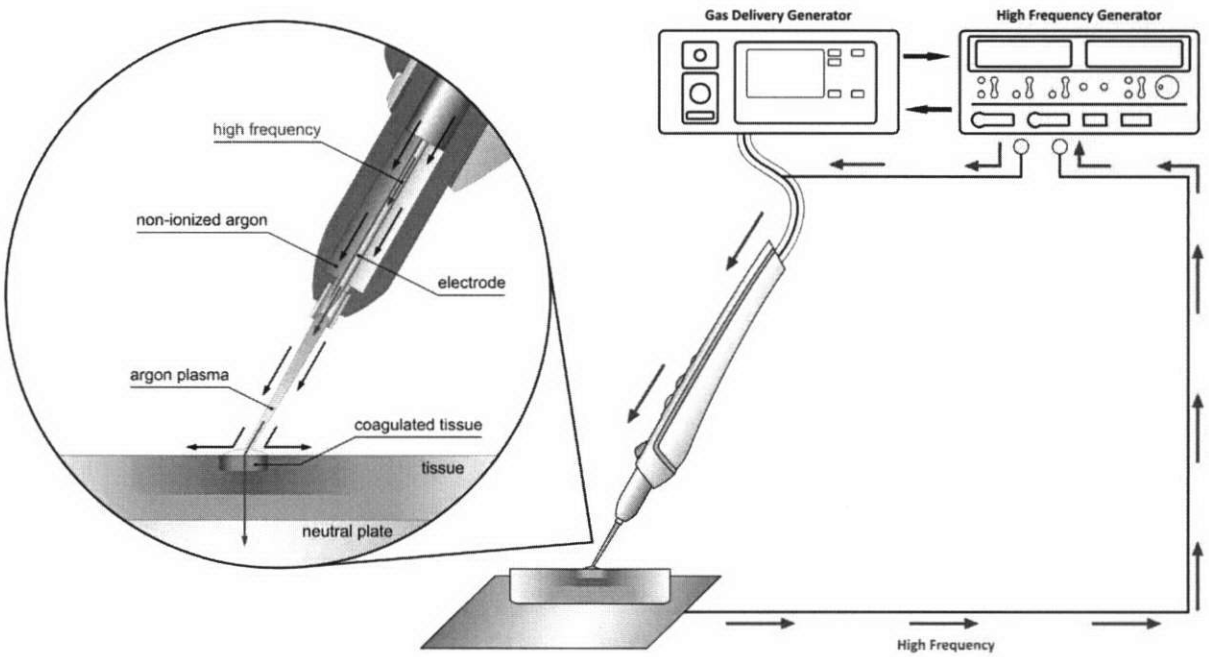


Figure 1: Canady Plasma™ Coagulator's effect on tissue

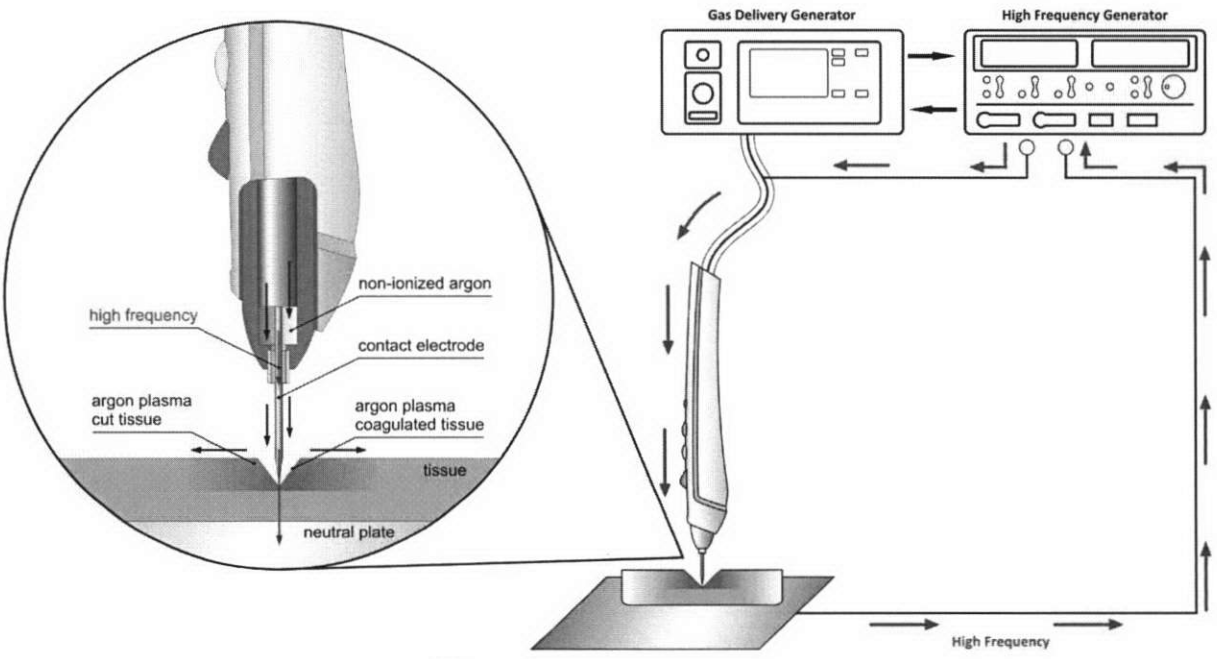


Figure 2: Canady Vieira Hybrid Plasma™ Cut effect on tissue

1.4 – Kit of accompanying accessories (suggested):

a) Cylinder

Figure 3: Cylinder

b) AW-FSXX double footswitch

Figure 4: AW-FSXX double footswitch

c) CA-XX probe

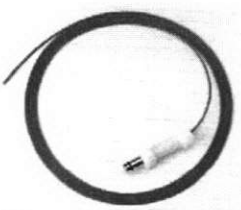


Figure 5: CA-XX probe

d) Transportation unit

Figure 6: Transportation unit

h) Operating Manual

Manufactured items to exclusive use in company products:
All the parts, accessories and optionals described in this operation manual, and others non-specified, are exclusive use with the company products.

Attention: *The User is entirely responsible for the use of any non-specified part, accessory, or materialwhich is not listed in this manual* US Medical Innovations assumes **no liability** in the event that unauthorized accessories are used with this equipment. **The warranty shall be rendered null and void if unauthorized (*not authorized by US Medical Innovations) accessories are attached to Canady Plasma™ Coagulator Argon 4.**

1.6 –Technical Specifications and Features:

Class (MDD 93/42)	Class IIb
Class (ANVISA)	Class III
Equipment dimensions (length x width x height)	Front: 300 mm Height: 140 mm Depth: 400 mm
Area required	0.048 m^3
Packaging dimensions	0.28 X 0.40 X 0.70 m
Packaging type	Cardboard
Net weight	7.3 kg
Gross weight	8.0 kg
Electric voltage supply range	100 VAC to 240 VAC with automatic voltage selection
Mains Frequency	50 Hz / 60 Hz
Current consumption	0.4 A (127 VAC mains) 0.3 A (220 VAC mains)
Current type	AC (alternating)
Number of phases	Single phase
Operating voltage selector	Automatic voltage selection
Operating Mode	Intermittent operation
Protection against electric shock	Applied part type CF Class I equipment
Protection against harmful ingress of water	Common equipment - IPX1 (Drip-proof enclosed equipment)
Rated input power	200 VA
Maximum electric power	200 VA
External fuses	2 A / 250 V
Type of fuses	Glass (model 20AG), 20 mm, quick action

Table 1: Technical Specifications and Features

THIS EQUIPMENT IS NOT SUITABLE FOR USE IN EXPLOSION-PRONE ATMOSPHERES

Detailed dimensions of equipment (mm):

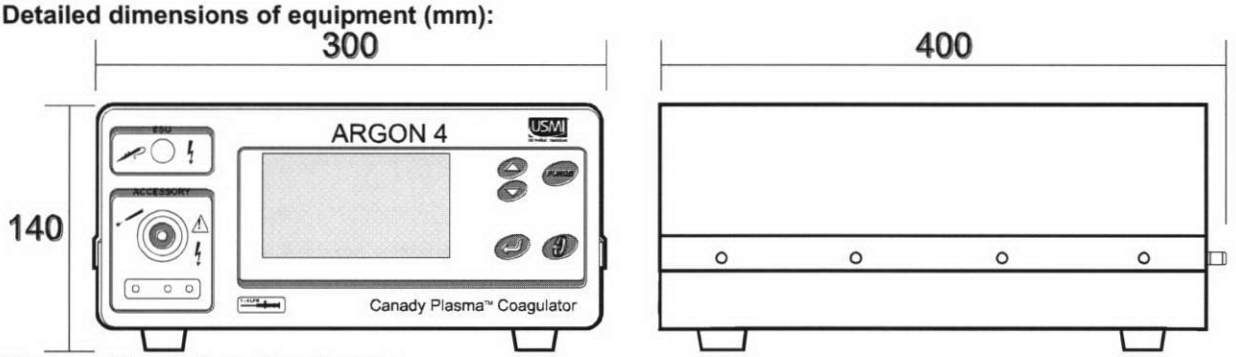


Figure 7: Dimensions of equipment

(Main) Standards applied to the equipment design and development

IEC 60601-1 Standard	– Electromedical equipment – Part 1 – General requirements for safety
IEC 60601-2-2	– Electromedical equipment – Part2 - 2: Particular requirements for the safety of high frequency surgical equipment
IEC 60601-1-2	– Electromedical equipment – Part 1 - 2: Collateral standard: Electromagnetic compatibility – Requirements and tests

(Main) Standards applied to the equipment manufacturing process

- ISO 9001 Standard	– Quality management systems – Requirements.
- RDC 59 (ANVISA) Standard	– Good Manufacturing Practices for Medical Products
- EN ISO 13485 Standard	– Quality systems – Medical devices – Particular requirements for the application of ISO 9001

CARE TO BE TAKEN WHEN USING ARGON GAS

Argon gas is an odorless, colorless, chemically-inert non-toxic noble gas, found in the atmosphere.

The cylinders to be connected must contain 99.998 % pure argon gas minimum. Maximum input pressure must not exceed 2900 psi (200 bar). The equipment is prepared to receive 2 argon gas cylinders.

Argon gas is non-flammable, but its cylinder may rupture due to fire or heat, and no part of its cylinder may be subjected to temperatures above 125 °F (52 °C); however, cylinders are fitted with a pressure-relief device. All precautions about handling and storage must be taken.

The cylinder must always be free from any risk of falling, must always be transported in a cylinder-carrying cart. Never drag, roll or let the cylinder fall. In case of leakage, close the valve, and with the equipment turned off, disconnect it from the Argon 4. Take the cylinder to a well-ventilated area and call the gas distributor to change or repair it.

2 – SPECIAL CONDITIONS FOR EQUIPMENT STORAGE, CONSERVATION AND/OR HANDLING

Storage: Keep it in a place protected from moisture, rain and direct sunlight, and in the original packaging.
In case of storing several boxes of packaged equipment, maximum stacking must be as indicated in the stacking symbol on the packaging.

Conservation: When in use, clean it with a moist cloth.
Keep the apparatus clean for the next use.
Do not allow liquids to be inserted into the apparatus.
Do not use organic solvent, such as thinner, to clean the apparatus.
Keep the apparatus in a clean place, away from dust.

Transport: When in the original packaging, during transportation, avoid vibrations and impacts to the apparatus, and do not drop it.

Symbols printed on the packaging related to storage and transportation.

	Position of packaging for storage and transportation		Maximum stacking load permitted
	Maximum stacking		Temperature limits
	Protect against water		Humidity limits
	Fragile contents		

Table 2: Symbols printed on the packaging

Transport conditions
Room temperature –40°C to 70°C (–40°F to 158°F)
Relative humidity: 10% to 100%
Atmospheric pressure: 500hPa to 1060 hPa (375 mmHg to 795 mmHg)

3 – INSTRUCTIONS FOR USE OF THE EQUIPMENT:

3.1 – Operating and storage conditions

The operating and storage conditions of the equipment are specified conforms with General IEC 60601-1 Standard (Section 2 - Item 10.2.1 Environmental conditions).

Room temperature range from +10 °C to +40 °C.
Relative humidity range from 30 % to 75 %
Atmospheric pressure range from 700 hPa to 1060 hPa (525 mmHg to 795 mmHg)

3.2 – Understanding the Front Panel of the Equipment

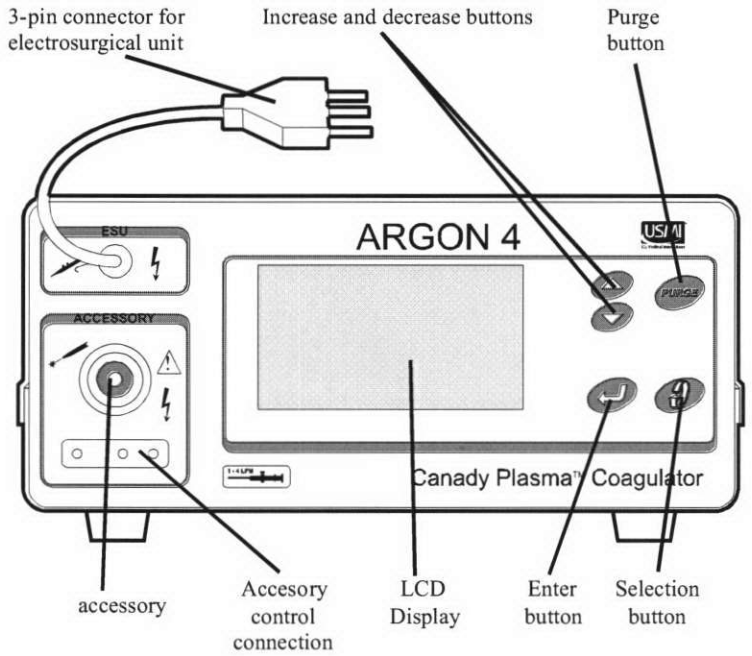


Figure 8: Front panel

3.3 –Understanding the Rear Panel of the Equipment

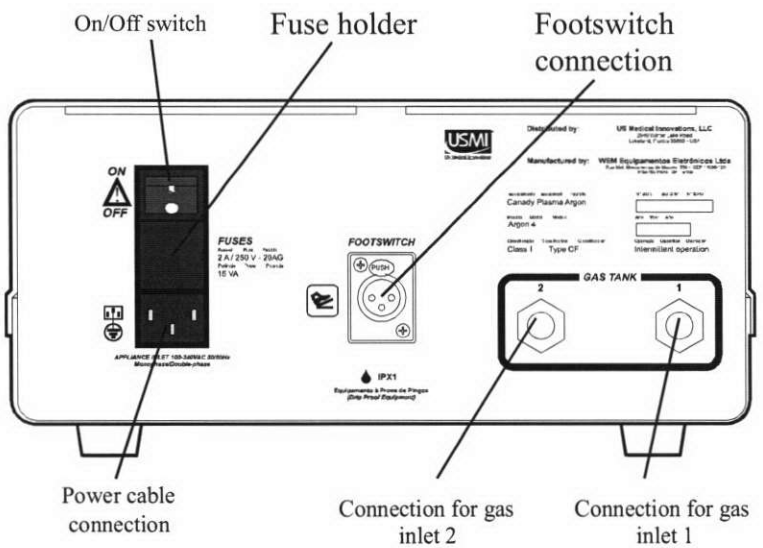


Figure 9: Rear panel

3.4 –Other symbols used on the equipment

Front Panel

	Before using the Argon 4, please refer to the accompanying documentation
	Purge control
	Indicator of argon coagulation activated
	High-voltage output
	Electrosurgical unit connection
	Connector for ES-10 handpiece, CA-01 catheter, etc.
	Indicated flow for laparoscopic procedures.

Rear Panel

	Connect the Argon 4 to grounded electric mains
	Footswitch connector
SN	Serial Number

Accessories

	Manufacturing Date
	Validity
	Disposable

Table 3: Symbols used on the equipment

3.5 –Operating the equipment

If the unit is correctly installed according to section 6, follow the instructions below:

1º: Connect the power cord supplied with the Argon 4 into the rear panel power cord connection. Do the same with the electrosurgical unit, if its cord is detachable.

*2º:*Place the On/Off switch located on the rear panel of the Argon 4 in the OFF position.
Place the electrosurgical unit switch also in the OFF position.

3º: Open the gas valve (see chapter 7.6), as indicated on the following screen, and press Enter.

*4º:*Connect the Argon 4 and the electrosurgical unit power plug to a grounded outlet (see chapter 7.3, 7.4, and 7.5).

*5º:*Place the Argon 4 On/Off switch in the ON position. After a few seconds, the LCD display on the front panel will come on, with the following image.

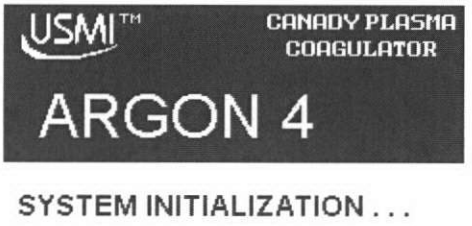


Figure 10: "system initialization" Argon 4 screen

*6º:*Switch the electrosurgical unit on.If the electrosurgical unit has a stand-by mode, leave it in operating mode for Monopolar/Coagulation (Spray).

If the equipment screen shows the following image, open the valve or change the cylinder, and press the "ENTER" button. The Argon 4 will restart the equipment's initial cycle, and screen will change to the operation mode.

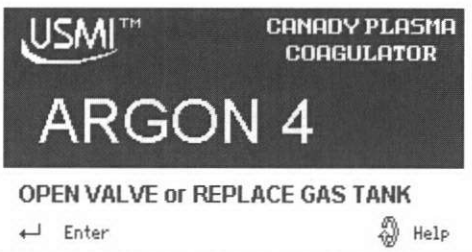


Figure 11: "open or change the gas cylinder" Argon 4 screen

*7º:*Adjust the gas flow through the increase or decrease buttons, located on the front panel of the Argon 4, or else press the selection button to select between the Cut or Coagulation mode

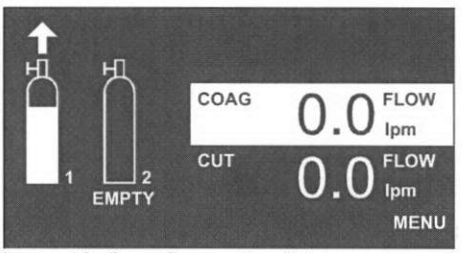


Figure 12: "gas flow adjust" Argon 4 screen

3.6 –Gas Purge

For this procedure, press the Purge button located on the front panel of the Argon 4, and the display will look like this, with the arrow on top of the cylinder indicating that gas is being used from or leaving the indicated cylinder. Whenever a cylinder is empty, it will be indicated as shown below.

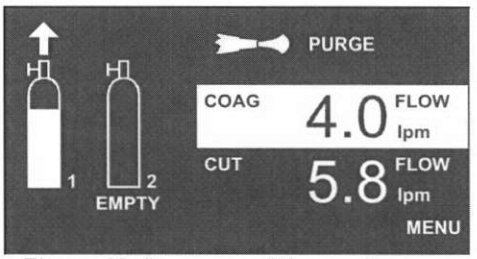


Figure 13: "gas purge" Argon 4 screen

Purging is necessary to expel the air out of the gas line and replace it with argon gas. Press the Purge button on the front panel of the Argon 4 before starting a procedure or whenever you replace an accessory; the Purge button must be pressed for approximately 10 seconds (this procedure will not actuate the electrosurgical unit). Next, make sure the flow index is adjusted to the desired levels according to the electrosurgical unit power levels or the surgeon's preference.

3.7 –Reconnected cylinders (new or reinstalled cylinders)

When the cylinder runs out of gas, the equipment emits a soft, discrete sound signal, every few seconds. Shortly before reaching the end, the interval between the sound signals decreases, until the gas contained in the cylinder is gone. Before replacing the cylinder (see Chapter 7.6) or after a cylinder is connected, press the Purge button on the Argon 4 front panel (the electrosurgical unit will not be activated). Next, make sure the flow index is adjusted to the desired levels according to the electrosurgical unit power or the surgeon's preference.

3.8 –Functions of the Menu screen

The Menu screen has icons that can be accessed. Through the Selection button, choose the desired icon, then press Enter to access the desired screen:

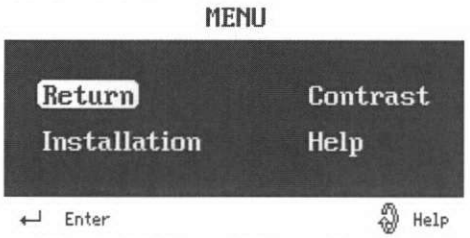


Figure 14: "menu" Argon 4 screen

- **INSTALLATION:***on this screen, the user can find information on how to install the Canady Plasma™ Coagulator model Argon 4; browsing through the screens is by means of the increase and decrease buttons. The Enter button will return you to the MENU screen. The information contained on this screen are also shown in this manual.*
- **CONTRAST:***the user can select the LCD display contrast level through the increase and decrease buttons. Pressing Enter will return you to the MENU screen.*
- **HELP:***offers a quick help guide with information on how to use the Argon 4 and Troubleshooting. Browsing is by means of the increase and decrease buttons. Pressing Enter will return you to the MENU. All the information on these screens is shown in this manual.*
- **RETURN:***pressing the Enter button on this Menu option will return you to the working screen of the* CanadyPlasma™ Coagulator model Argon 4.

3.9 –Starting Coagulation with Argon Gas

The Argon 4 and the electrosurgical unit must be installed as per section 6.0.In order to perform coagulation with argon gas, you must press the COAG lever on the footswitch.

CANADY PLASMA™ BEAM INITIATION. Start the argon gas beam by holding the tip one centimeter (1/2 inch) from the patient's tissue. Once the beam is initiated, the tip of the hand device may be positioned at a certain distance from the target tissue to provide a more comfortable position and to obtain the desired beam. An angle of 45° to 60° between the handpiece and the tissue surface is recommended to obtain optimum performance. Note also that the tip will glow if it is too close to the tissue or if the electrosurgical unit power is excessively high.

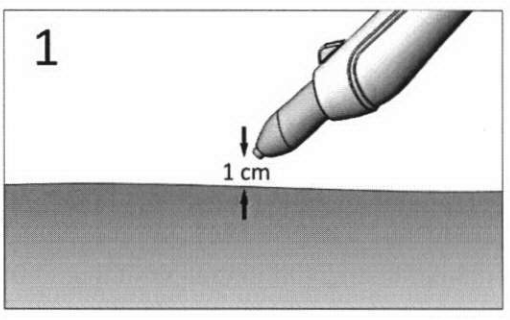


Figure 15: Handpiece distance for Canady Plasma™ Beam Initiation

CANADY PLASMA™ BEAM INITIATION depends on several variables, such as electrosurgical unit output voltage, tissue type and/or handpiece or accessory type, start the argon gas beam by holding the tip one centimeter (1/2 inch) from the patient's tissue. Once the beam is initiated, the tip of the hand device may be positioned at a certain distance from the target tissue to provide a more comfortable position and to obtain the desired beam. An angle of 45° to 60° between the handpiece and the tissue surface is recommended to obtain optimum performance. Note also that the tip will glow if it is too close to the tissue or if the electrosurgical unit power is excessively high.

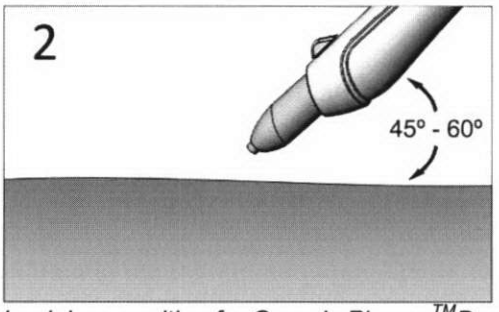


Figure 16: Handpiece position for Canady Plasma™ Beam Initiation

Keep the handpiece at an angle between 45° and 60° in relation to the tissue. This allows the gas flow to keep blood and debris away from the surgery site.

IMPORTANT: Do not point the tip at open vessels. Do not try to coagulate vessels larger than 3 mm in diameter.

BEAM EXTINGUISHED: If the beam is extinguished while being moved away from the tissue, this means that the electrosurgical unit's capability to maintain a conducting channel of ionized argon gas has been exceeded; the tip must be held closer to the patient's tissue to continue with coagulation.

The lower the electrosurgical unit energy level or the peak-to-peak voltage the lower the distance between the tip and the tissue must be in order to initiate ionization of the argon beam.

3.10 –Activation of theCanady Vieira Hybrid Plasma™ Scalpel.

The handpiece consists of three major components: Handle, Telecscoping Nozzle, and Electrode. The insulated handle encases the high frequency(HF) current and gas tubing for controlling the flow of argon gas and activation of HF current for the device. HF current is activated by two push buttons yellow (standard **CUT** mode) and blue (standard **COAG** mode) which are on top of the handle. Argon gas is delivered via the handle by activating a third push button (purple) which is also on top of the handle. Depending on the RF current mode (**CUT** or **COAG**), the handpiece can function in the following plasma modes: **HYBRID PLASMACUT** – First push the purple button to activate the gas delivery afterwards press down on the yellow button to start Hybrid Plasma Cut. Hybrid Plasma Cut mode will cut and coagulate the tissue at the same time. To switch back to standard cut mode press down on the purple button afterwards press down on the yellow button to cut.**ARGON PLASMA COAGULATION (APC**) – First push the purple button to activate the gas delivery afterwards press down on the blue button to start Argon Plasma Coagulation.To switch back to standard **COAG** mode press down on the purple button afterwards press down on the blue button to start coagulation. Canady Plasma™ Argon 4 provides a controlled flow of argon to the electrosurgical handpiece during Hybrid Plasma Cutting or Argon Plasma Coagulation modes. The physician manually sets the flow rate on the plasma coagulator and power (watts) on the electrosurgical generator. The telescoping nozzle can be extended or shortened over the electrode as desired when the surgeon is performing plasma procedures. The electrode tip delivers RF energy for standard **CUT, COAG, ARGON PLASMA COAG** and **CANADY VIEIRA HYBRID PLASMA™ CUT.**

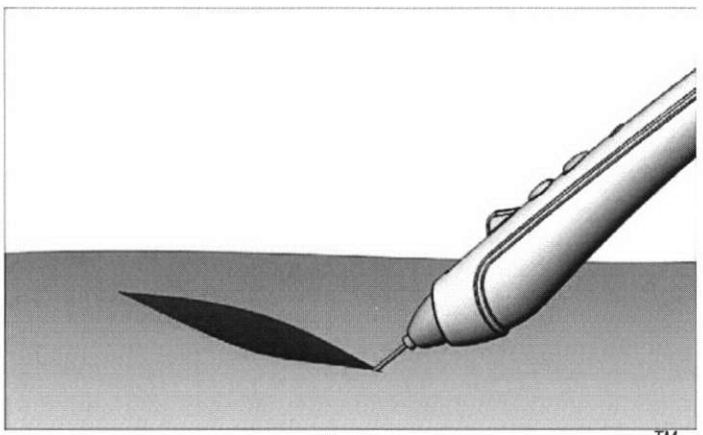


*Figure 17: Handpiece position for Canady Vieira HybridPlasma™*Scalpel

NOTE: Closed the argon gas cyclinder prior to removing the gas cylinder for replacement.

Before any surgical procedure, check the argon gas pressure. Replacement of the empty cylinder is recommended as soon as indicated on the screen. To replace the cylinder, refer to chapter 7.6 of this manual.

4 –WARNINGS AND/OR PRECAUTIONS TO BE TAKEN

4.1 –Warnings and/or precautions during transportation and storage

During transportation (packaged product), avoid vibration and impact to the equipment.
Do not leave the equipment exposed to rain or to excessive moisture. Avoid falls (packaged product).

When the equipment is not used for a prolonged period of time, removing the plug from the electric outlet is recommended, and the cylinder(s) must be closed.

Cylinders must be well fastened to transportation units. Never roll the cylinder, and protect it from falls, excessive heat or fire.

4.2 –Warnings and/or precautions during installation

Never install the equipment near water faucets or similar devices. Do not install the equipment close to abnormal atmospheric pressure and temperature, high moisture, intense sunlight, poor ventilation, alkaline or acid environment, dust, chlorine and sulfuric acid.

Make sure the equipment is only installed at stable sites. Make sure the equipment is in a safe place in terms of tilting, vibration or shocks.

Check whether the equipment voltage and frequency match those of the local electric mains. If necessary, the equipment must be switched to the same rating as that of the local electric mains.
Check whether the mains where the equipment is to be connected are duly grounded.

For safety reasons, check and make sure that the equipment is not connected to the electric mains during installation.

Check whether the cylinder is in the correct position and well fastened to the equipment transportation unit and that there are no leaks at the connections.

4.3 –Warnings and/or precautions during use

Do not use this equipment or part of it for a purpose for which it was not designed. Do not modify the equipment.

Never attempt to repair the equipment; call the authorized technical service.

Never yank the output power cable.

The product may only be used or operated by a qualified professional (physician) or under his/her supervision.

The warranty shall be rendered null and void if unauthorized (*not authorized by US Medical Innovations, LLC) attempt to repair the equipment. US Medical Innovations, LLC assumes no liability for unauthorized attempts to repair the equipment.

4.4 –Warnings, recommendations and care during surgical procedures

Check all the accessories and connections to Argon 4 and the electrosurgical unit before starting the procedure. Make sure all accessories are working properly. Inadequate connections may produce metal-to-metal sparking, thus resulting in neuromuscular stimulation to the patient, accessory malfunctioning and undesirable surgical effects.

Electrosurgery must be cautiously used on patients with internal or external pacemakers. The interference produced by the electrosurgery current may cause improper functioning of the pacemaker. For further information, a cardiologist or the pacemaker manufacturer must be consulted.

The patient must not be allowed to get in direct contact with grounded metallic objects (surgery table, instrumentation tables, etc.) during the electrosurgery in order to avoid burns due to current deviations. When this is not possible, care must be taken in order to assure the patient's safety. The use of antistatic sheeting is recommended for this purpose.

The contact between body parts may result in burns due to the circulation of electrosurgical current between these parts. Dry gauze or dressing must be used in order to separate them.

In cases where an electrosurgical unit or Argon 4 fault or malfunctioning may cause a surgery to be interrupted, a spare unit should be kept in proper condition to be substituted.

Special care must be taken when using electrosurgery very near or in direct contact with metallic objects such as forceps, specula, clamps, etc. The use of electrosurgery in these conditions may cause tissue destruction and unintentional burns.

Use the minimum power level required for the surgical procedure in question. In case the surgeon does not have any personal experience in relation to the power level to be used, we recommend starting at a very low level and carefully increasing it until the desired electrosurgical effect is achieved. Never increase the power level without previously making a careful examination of the handpiece, plate cable conditions as well as their respective connections. The need for a high increase in power may indicate problems in the cables or in their connections. Use the active electrode as little as possible to obtain the desired surgical effect so as to reduce the possibility of burns.

The cables of the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided.

Sparking and heat generation associated with electrosurgery may constitute an ignition source for flammable materials such as:

a. Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen, if a surgical procedure is carried out in the chest or the head, unless these agents are removed by suction.
b. Accumulation of flammable solutions under the patient or in body depressions or cavities such as the navel area or the vagina. Any fluid accumulated in these areas should be removed before the equipment is used.
c. Endogenous gases.
d. Hydrophilic cotton or gauze saturated with oxygen.
e. Inflammable substances such as alcohol-based dyes used in preparing the patient for surgery.
f. Inflammable natural gases which may accumulate in cavities, such as the bowels.
g. Adhesive products such as inflammable solvents.

Whenever possible, use non-flammable agents for cleaning and decontamination. Otherwise, wait until the flammable agents used for cleaning or disinfecting evaporate before performing high-frequency surgery.

Dangerous voltage levels.This equipment must be used only by qualified personnel.

Never use it for endometrial ablation. High risk of air/gas embolism inside the uterus.Do not aim the jet into open vessels.

Use it with care near delicate tissues such as the intestine, bladder, ureter, major vessels.

4.5 – Caution During Endoscopic and Laparoscopic Procedures

If the electrosurgical unit is unintentionally activated or moved out of visual range while activated, patient injury may result.

Continually monitor intra-abdominal pressure during activation of Argon 4, without letting it exceed 18 mmHg.

4.6 –Care with accessories

Before each use, check the conditions of the electrode cables (handpiece, clamp, etc.) and observe their isolation (overdrying, cracking, failures), broken cables, broken connector, etc. Repair or replace them in order to avoid safety risks to the patient as well as to the operators.

Adhesive plates must be discarded after each use.
Do not wrap the patient plate or accessory cables around metallic objects. This procedure may induce potentially dangerous currents in these objects, which may cause shock and burns to the patient or to the operating team.

Do not connect wet or internally humid accessories to Argon 4. There may be a risk of electric shock.

An apparently low power output or failure in equipment operation under normal operating settings may indicate faulty application of the neutral electrode or poor contact in the connections (see chapter 7.7).

4.7 – Warnings and/or precautions during cleaning

Prior to cleaning the equipment, verify that it is switched off.
For external cleaning of the apparatus, use a damp cloth. Be careful not to allow any liquid to enter the equipment. If entrance of liquid cannot be avoided, do not turn the equipment on and call the Authorized Service Dealer immediately.
Do not use micro abrasive material or a steel sponge to clean it, nor use organic solvents or detergents containing solvents such as ether, stain remover, gasoline, etc.
Do not use aerosols or liquid spray dispensers.

5 – EQUIPMENT PERFORMANCE AS TO ESSENTIAL SAFETY REQUIREMENTS AND EFFECTIVENESS OF MEDICAL DEVICE, AND POSSIBLE UNDESIRABLE SIDE EFFECTS

5.1 – Indication, purpose or use for which the equipment is designed:

Indication: Canady Vieira Hybrid Plasma™ is intended for use in open surgical procedures and where monopolarelectrosurgery (cutting and coagulation) in normally used

Purpose: Hybrid Plasma cutting and enhanced coagulation of biological tissues through the use of argon gas

5.2 – Undesirable secondary or side effects and contraindications:

The equipment does not produce any undesirable secondary or side effect if all recommendations in this Operating Manual are followed. The equipment has no contraindication. The product may only be used or operated by a qualified professional (physician) or under his/her supervision.

5.3 – Equipment safety and effectiveness:

The equipment is totally safe if the Operating Manual instructions are followed.

6.0 – INSTALLATION OR CONNECTION

The Argon 4 must be utilized with US Medical Innovations, LLC Electrosurgical Unit(ESU) SS-601MCa having the "Spray" coagulation (fulguration) mode at a minimum 5000 VPP voltage.

The Argon 4 allows different US Medical Innovations electrosurgical units to be safely positioned on the rear (top) portion of the module.

The feet of the electrosurgical unit must be fitted into the existing grooves on the top of the Argon 4, in order to avoid accidentally moving the unit. These 4 grooves were specially designed to accept the grooves of US Medical Innovations *SS-601MCa* electrosurgical unit.

To install the Canady Plasma™ Coagulator model Argon 4:

1º:Make sure the Argon 4 and the electrosurgical unit are disconnected from the electric mains.
2º:Plug the 3-pin connector on the Argon 4 front panel into the socket for the electrosurgical unit manual-control handpiece.
3º:Connect the footswitch to the connector on the Argon 4 rear panel.
4º: Connect the accessory to the socket on the Argon 4 front panel.

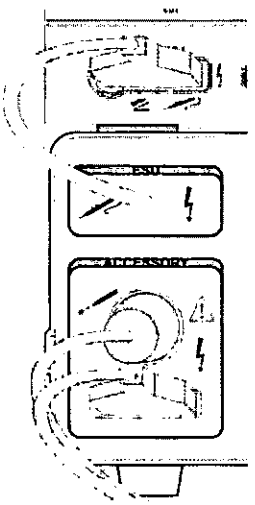


Figure 18: Installation of electrosurgical unit and accessories

Attention:
The User is entirely responsible for the use of any non-specified part, accessory, or material.
Warning: The User shall be entirely and solely responsible for the use of unspecified parts, accessories or materials. Note: US Medical Innovations assumes no liability in the event that unauthorized accessories (**not authorized** by US Medical Innovations, LLC) are used with this equipment. **The warranty shall be rendered null and void if authorized argon accessories (*not authorized by US Medical Innovations) are attached to the Canady Plasma Argon 4 or if unauthorized repairs (*not authorized by US Medical Innovations) are made or attempted on the product.**

7 – INSTALLATION, CORRECTIVE AND PREVENTIVE MAINTENANCE

7.1 – Equipment Installation

After unpacking the Argon 4, make sure there is no apparent damage caused by shock or improper handling during transportation. If so, get in contact with the transportation company immediately for information on what measures to be taken.
US Medical Innovations is held responsible for the safety, reliability and performance of the equipment as long as:

a. The equipment is used according to the operating instructions contained in this manual.
b. The electric wiring is in accordance with the U.S. regulations in force for hospital facilities.

7.2 –Use With a Transportation Unit

The transportation unit is an optional accessory. In case it has been purchased, position the Argon 4 on it, as shown in the above figure. If the cart has not been purchased, place the Argon 4 on a suitable type of support.
Move the transportation unit always together with the equipment when transporting over uneven surfaces. After the unit is positioned in place and in use, avoid moving it so as not to disconnect the electrode cables or the power supply cord.

7.3 –Power Plug

The power cord plug supplied with the equipment is of the 3-pin type, 2 flat and 1 round hospital grade NEMA 5-15P, IEC 320 / C13 Connector. The round pin must be connected to the ground. If the power outlet at your surgical center is different from that supplied and provided it has the ground terminal (NEMA 3P or other type), the manufacturer must be contacted to provide the proper power cord or to change the outlet in order to utilize the cord supplied with the equipment.***Extension wires or three-to-two pin adapters without grounding pin must not be used***. Regular inspections of the power cord must be carried out in order to check for damages in isolation or in the connectors. When unplugging the equipment, always pull by the plug and never by the cord.

7.4 –Grounding

In order to ensure patient as well as surgeon safety, the Argon 4 must be conveniently grounded.The ground wire in the power cord is connected to the equipment frame, thus preventing the circulation of dangerous currents coming from the equipment box in case of a power failure.If the site where the equipment will be utilized is not fitted with adequate grounding, this must be provided before the unit is switched on.

7.5 –Mains Voltage

The Argon 4 can be connected to any power outlet whose voltage rating is between 100 VAC and 240 VAC. In case of doubt, check with qualified personnel. Check whether the fuse complies with the specification printed on the rear panel of the equipment or is in accordance with chapters 1.6 and 7.7.

7.6 –Installation of Cylinder

The cylinders to be connected must contain 99.998% pure argon gas minimum. **Only commercially availableARGON 4.8 gas cyclinders are to be used with the USMI Electrosurgery Unit**. Maximum input pressure must not exceed 2900 psi (200 bar). Do not remove the safety seal or the cover of the equipment. **The warranty shall be rendered null and void if there is any unauthorized removal of safety seal, cover, repairs of the equipment or attempted repair on the product.** The equipment is prepared to receive 2 argon gas cylinders; however, it can be connected to only 1 cylinder. In this case, connect the cylinder to any of the Argon 4 inlets.
1º:Place the argon gas cylinders on the bottom of the rear portion of the transport unit.
2º: Connect the gas hoses to the rear portion of the Argon 4 and tighten them by hand.
3º: Align the cylinder fittings with the gas connector hoses.
4º: Fasten the cylinders to the cart using the clamps that come attached to the cart.
5º: Connect the hoses to the cylinders by hand.
6º:Open the gas valves. A short hissing sound will be heard when the valve is opened. If this sound lasts longer than 2 seconds, close the valve immediately and check for any incomplete and/or misaligned connections. If the problem persists, please contact US Medical Innovations Technical Service.

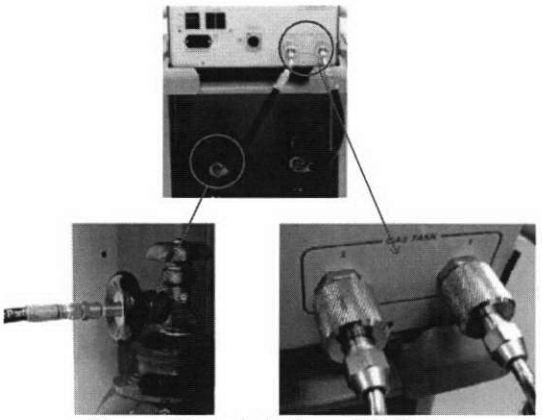


Figure 19: Installation of Cylinder

7.7 –Corrective maintenance

PROBLEM	SOLUTION
The equipment does not switch on	- Check if the power cable is connected to the electric mains - Check if the outlet has electric power - Check if the power cable is not broken - Check if the switch is not damaged - Check if the fuses on the rear panel are burnt; if so, with the equipment switched off, replace them
Gas leakage	- Internal leak in equipment. Turn the equipment off and on; if the "gas leakage" message persists, see US Medical Innovations Technical Service.
The equipment burns fuses	- Check if the fuse amperage matches that of the indicator - Check if the cabling or any connection contact is not shorted
Equipment has no power output	- Check if the footswitch is properly connected - Check if the 3-prong connector is properly connected to the generator output. - Check if the accessory (handpiece, catheter, etc.) is properly connected to the Argon 4 output. - Make sure the accessory is in good condition. - Check if there is any pressure in the cylinder or if the output flow is adjusted. Otherwise, open the cylinder valve or adjust the output flow. - Check if the generator is switched on. - Check if the generator is out of the stand-by status or if its power is adjusted.
Generator plate failure alarm actuated	- Check if the plate cable is properly connected to the plate and to the generator. - Replace the plate cable with another one that has been proven to be faultless.
Neuromuscular stimulation	-Stop the surgery. -Check all accessory connections and make sure there is no faulty contact. -Lower power levels reduce neuromuscular stimulation. -Fulguration tends to produce more neuromuscular stimulation than cutting due to the higher voltage levels involved. -Desiccation should not produce neuromuscular stimulation because there is no sparking involved.
Interference with the heart monitor	- Check if the power cord ground wires in the apparatuses involved are not broken. - Check the integrity of the frame-ground connection for the Argon 4, generator and the monitor. - Check if the electric wiring grounding circuit in the surgery room is adequate. - Check the plate cable and accessory connections. Metal-to-metal sparking resulting from faulty connection may cause interference. - Fulguration tends to produce a higher level of interference than cutting. Lower power levels produce less interference.
Interference with pacemakers	- Check the plate cable and accessory connections. Metal-to-metal sparking resulting from faulty connection may cause interference. - Preferably use bipolar instruments. - When using monopolar instruments, place the patient plate as close as possible to the surgery area and keep the path traveled by the current as far away as possible from the heart muscle.

Table 4: Corrective maintenance

Note:*If the problem cannot be solved with the solutions given above, request the Authorized Dealer Service through US Medical Innovations Customer Service Department at 863 667-1609, fax 863 667-1917, or refer to the List of Authorized Dealer Services that comes with the equipment.*

Electro-electronic diagrams, parts list, and technical information.
The electro-electronic diagrams, parts lists and any other necessary information may be provided by US Medical Innovations, LLC, provided they are necessary for the technical upkeep of the equipment by the user, after mutual agreement between the parties.

Warranty Conditions

WARRANTY
The warranty is limited to replacement and/or repair of any defective parts or the correction of any manufacturing defect, upon verification by our Technical Service Department.

The replacement and/or repair referred to in the previous item does not apply to worn parts due to regular use (fuses, etc.), as well as failure due to misuse or negligence when using the equipment, or else to parts that have been repaired or modified by personnel not authorized by US Medical Innovations.

Original warranty shall not be extended due to replaced component.

EQUIPMENT
This warranty is valid for all US Medical Innovations brand equipment manufactured by US Medical Innovations, LLC

INSTALLATION AND USE
The installation and/or operation of the equipment as well as working conditions must comply with the US Medical Innovations rules contained in this Operating Manual. Conditions different from those indicated, **the warranty shall be null and void.**

WARRANTY LOCATION
The US Medical Innovations-certified Authorized Technical Service shall carry by a US Medical Innovations technician or repair and/or replacement of the parts.

Whenever it is found that a repair of the equipment can only be achieved at our facilities (factory) or by the technical representative authorized by us, the transportation cost (both ways) shall be borne by the purchaser.

WARRANTY PERIOD
Warranty begins on the date when the product is delivered and accepted by the purchaser. The warranty is valid for 24 months.
RESPONSIBILITY
This warranty is valid only for the equipment that is under use and possession of the original purchaser.

US Medical Innovations' responsibility is limited to replacing and/or repairing the components, with possible losses due to lost profits or indemnification for any other indirect or immediate damages being excluded from the warranty.

Request the Authorized Dealer Service through US Medical Innovations Customer Service Department at 863 667-1609, fax 863 667-1917, or refer to the List of Authorized Dealer Services that comes with the equipment.

7.8 –Preventive Maintenance and Conservation:

Preventive Maintenance
On a daily basis, check:
- if there is oxidation on the power cords
- if uncommon odors occur when the equipment is switched on
- If there is no physical damage to the equipment housing

On a weekly basis, check:
- the conditions of the power source (electric mains outlet)
- if there are leaky cylinder connections

On a semi-annual basis, preventive maintenance is recommended. During that semi-annual preventive maintenance, replacement of the high-efficiency (HEPA) internal filter is recommended, due to impurities or particles that may be found in low-quality argon gas cylinders.

The filter is designed to retain impurities or particles, and must be changed every semester in order to ensure argon gas purity and to improve equipment efficiency. Preventive maintenance must be performed by US Medical Innovations or one of its Authorized Service Dealers.

Conservation

For external cleaning of the apparatus, use a damp cloth. Take care not to allow any liquid to enter the equipment. In case entrance of liquid cannot be avoided, do not turn the equipment on and call the authorized service dealer immediately.

Do not use microabrasive material or a steel sponge to clean it, nor use organic solvents or detergents containing solvents such as ether, stain remover, gasoline, etc.

Do not use aerosols or liquid spray dispensers.

Keep the apparatus in a clean place, away from dust.

Internal Description

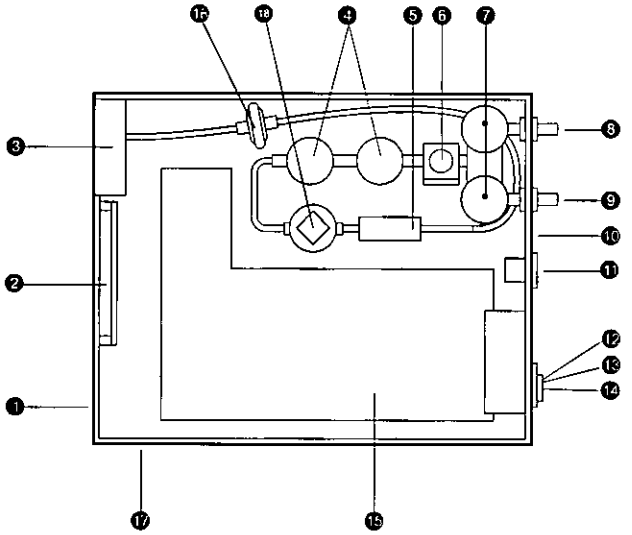


Figure 20: Internal View of Argon 4

❶ Front panel (CPU circuit board).
❷ Display
❸ Output panel
❹ Reducing valves
❺ Flow regulator
❻ Pressure sensor
❼ Solenoid valves
❽ Connection to tank no. 1
❾ Connection to tank no. 2
❿ Rear panel
⓫ Footswitch connector
⓬ Fuse holder
⓭ Connector for detachable power cord
⓮ On/Off switch
⓯ MB circuit board
▯ Filter
⎽ Box base
⏚ Security valve

The Argon 4 has a self-test system to check whether the solenoid valves are leaking or damaged (see item 1.3). The Argon 4 internal checking test is performed in this sequence:

1) *When the Argon 4 is turned on, the equipment purges all the argon gas in the lines.*
2) *The gas is purged until the sensor detects that the internal pressure reached zero (0).*
3) *After this procedure, the equipment opens solenoid valve 1, fills the lines and automatically measures and stores the pressure in the lines, which is called X_1.*
4) *After storing the X_1 value, the equipment closes solenoid valve 1, and measures the line pressure again after 10 seconds. This value is called X_2.*

5) *The Argon 4 compares the values of X_1 and X_2; if there is a difference between these two values, the LCD screen shows the message "GAS LEAKAGE", and blocks its use. If there is no difference between these values, the Argon 4 purges the gas in the lines.*

6) *After checking solenoid valve 1, the equipment performs the same procedure in solenoid valve 2.*

After the two solenoid valves are checked, the Argon 4 is ready for use, indicating on the LCD screen the cylinder with lower amount of gas.

8 – ADDITIONAL PROCEDURES FOR ACCESSORY REUTILIZATION

Cleaning and Sterilization Methods

A. *Cleaning with water and neutral soap*

B. *Sterilization by autoclave or gas*

Description	Method
Argon handpiece	All
Argon catheter	All
Argon electrode	All
Adapter	All

Table 5: Cleaning and Sterilization methods for accessories

*Sterilization by germ-killing solutions, like **Glutaraldehyde,** is not recommended because it's very corrosive and can damage stainless steel and silica accessories.

Packaging

Keep it away from rain or excessive moisture.

When the equipment is not used for a prolonged period of time, removing the plug from the electric mains outlet is recommended, and closes the valve of the cylinders.

9 – ADDITIONAL PROCEDURES BEFORE USING THE EQUIPMENT

Even during its first use, the equipment must be cleaned, following the same additional procedures for reutilization, as described in item 8 of the Operating Manual.

10 – PRECAUTIONS IN CASE OF ALTERATION IN EQUIPMENT OPERATION

In case the equipment presents abnormal heating or noise, check if the problem is related to any of the causes listed in item 7.7 – Corrective Maintenance and immediately stop using the equipment.

In any case, check if the problem or alteration is related to any of the causes listed in item 7.7 – Corrective Maintenance. If the problem cannot be solved, call the Authorized Technical Service.

In this case, switch the equipment off, remove the power cord from the electric outlet and call the technical service through the US Medical Innovations Customer Service Department at *863 667-1609, fax 863 667-1917.*

11 – Electromagnetic compatibility

Guidelines ad manufacturer's certificate – electromagnetic emission			
The Argon 4 argon plasma coagulator is designed for use in electromagnetic environments such as described below. The user must make sure these conditions apply.			
Emission test		**Conformity**	**Electromagnetic environment - guide**
RF emissions IEC CISPR 11		Group 1	The Argon 4 argon plasma coagulator uses only RF energy for its internal functions. However, its RF emissions are very low and they are unlikely to cause interference with nearby electronic equipment.
RF emissions IEC CISPR 11		Class A	The Argon 4 argon plasma coagulator is suitable for use in all non-residential areas and those that are directly connected to the low voltage public mains that feed residential buildings.
Harmonic emissions IEC 61000-3-2		Class A	
Emissions due to fluctuations in sparking discharges IEC 6100-3-3		Conform	

Table 6: Electromagnetic emission

Guildelines ad manufacturer's certificate – electromagnetic emission			
The Argon 4 argon plasma coagulator is designed for use in electromagnetic environments such as described below. The user must make sure these conditions apply.			
Immunity test	**ABNT IEC 60601 test level**	**Conformity level**	**Electromagnetic environment - guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV per contact ± 8 kV through the air	± 6 kV per contact ± 8 kV through the air	Wooden, concrete or ceramic tile floors. If floors are covered with synthetic material, relative humidity must be at least 30%.
Electrical fast transient/burst immunity IEC 61000-4-4	± 2 kV in feed lines ± 1 kV in input/output lines	± 2 kV in feed lines ± 1 kV in input/output lines	The quality of power supply must be typical of hospital or commercial facilities.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of power supply must be typical of hospital or commercial facilities.

Table 7: Electromagnetic emission #2

Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment - guidelines
Voltage drops, short interruptions and voltage fluctuation in feed input lines IEC 61000-4-11	< 5% U_T (> 95% voltage drop at U_T) per 0.5 cycle. 40% U_T (60% of voltage drop at U_T) per 5 cycles. 70% U_T (30% of voltage drop at U_T) per 25 cycles. < 5% U_T (> 95% of voltage drop at U_T) per 5 seconds.	< 5% U_T (> 95% voltage drop at U_T) per 0.5 cycle. 40% U_T (60% of voltage drop at U_T) per 5 cycles. 70% U_T (30% of voltage drop at U_T) per 25 cycles. < 5% U_T (> 95% of voltage drop at U_T) per 5 seconds.	The quality of power supply should be typical of hospital or commercial facilities. If the equipment user requires continual operation during power cuts, it is recommended that the equipment should be fed by uninterrupted power supply or batteries.
Magnetic field at feed frequency (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at feed frequency should be typical of hospital or commercial environments.
NOTE: U_T is the AC feed voltage before the application of test level			

Table 8: Immunity Test

Manufacturer's guidelines and certificate - electromagnetic immunity

The Argon 4 argon plasma coagulator is designed for use in electromagnetic environments such as described below. The user must make sure these conditions apply.

Immunity test	NBR IEC 60601 ABNT test level	Conformity level	Electromagnetic environment - guidelines
IEC 61000-4-6 Conducted RF IEC 61000-4-3 Radiated RF	3 Vrms 150 KHz to 80 MHz 3 Vrms 80 MHz to 2,5 GHz	3 V 3 V/m	Portable or mobile RF communication device should not be used near any part of the equipment, including cables, and the minimum recommended separation, calculated according to this equation, applicable to the transmitter's frequency... Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the transmitter's maximum nominal output power in Watts (W), according to the manufacturer, and d is the recommended separation distance in meters (m). It is advisable that the field intensity produced by the RF transmitter, as determined through local electromagnetic inspection, [a] be lower than the conformity level for each frequency band.[b] Interference may occur in the vicinity of equipment marked with this symbol:

NOTE 1: For 80MHz and 800MHz, the higher frequency band should be used.
NOTE 2: These guidelines may not apply to all situations. The electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

[a] The intensity of the field produced by fixed transmitters, such as basal radio stations, telephone (cell phones and cordless) and mobile land radios, ham radios, AM and FM radio transmission and TV transmission cannot be theoretically forecast with much precision. To assess electromagnetic environments due to fixed RF transmitters, it is advisable to inspect sites for electromagnetism. If the filed intensity at the site where the equipment is to be used exceeds the conformity levels above, the equipment must be inspected to verify if it is functioning normally. If abnormal operation is observed, additional procedures may be required, such as reorientation or relocation.
[b] Above the frequency band of 150KHz to 80MHz, the intensity of the field is supposed to be lower than 3V/m.

Table 9: Electromagnetic immunity

Recommended separation distances between portable or mobile RF communication devices and the Argon 4 argon plasma coagulator

The Argon 4 argon plasma coagulator is suitable for use in electromagnetic environments in which RF radiated perturbations are controlled. The user can help prevent electromagnetic interference by keeping the recommended minimum distance between portable or mobile RF communication devices (transmitters) and the equipment, as prescribed below, according to the maximum power of such devices

Transmitter's maximum nominal output power W	**Separation distance according to the transmitter's frequency**		
	150KHz to 80MHz	80MHz to 800MHz	800MHz to 2,5GHz
	$d = 1{,}2\sqrt{P}$	$d = 1{,}2\sqrt{P}$	$d = 2{,}3\sqrt{P}$
0,04	0,24	0,24	0,46
0,4	0,76	0,76	1,45
4	2,4	2,4	4,6
40	7,6	7,6	14,5
400	24	24	46

For transmitters with unlisted maximum nominal output power, the separation distance d in meters (m) can be established through the equation that is applicable to the transmitter's frequency, where P is the transmitter's maximum nominal output power in Watts (W) according to the manufacturer.
NOTE 1: For 80MHz and 800MHz, the higher frequency band should be used.
NOTE 2: These guidelines may not apply to all situations. The electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

Table 10: Recommended separation distances

12 – SENSITIVITY TO FORESEEABLE ENVIRONMENTAL CONDITIONS UNDER NORMAL WORKING CONDITIONS

The Canady Plasma™ Coagulator model Argon 4 was designed not to be sensitive to interferences such as magnetic fields, external electric influences, electrostatic discharges, or pressure variation, provided the equipment is installed, maintained, cleaned, kept, transported and operated according to this Operating Manual.

13 – PRECAUTIONS IN CASE OF EQUIPMENT DISPOSAL

At the end of its useful life, the equipment and accessories should be disposed. US Medical Innovations, LLC is not responsible for improper disposable of equipment and accessories.

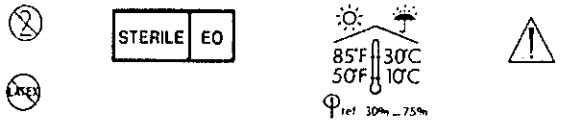
- *Contamination*
- *Improper use after extended life time of the equipment can result in faulty operation of the equipment and accessories attached to the equipment can cause injury to the patient and user.*

14 – LIST OF FIGURES AND TABLES

Relation of figures and tables used in this manual.

Canady Vieira Hybrid Plasma™ Scalpel
VW-422552

For Use only with USMI Canady Plasma™ Coagulators Argon 2 and Argon 4 and Canady Plasma™ Electrosurgical Generators SS-200E and SS-601MCa



Caution: Federal Law (USA) restricts the device to sale by or on the order of a physician. Device should only be used by physicians trained with electrosurgical pencils.

Instruction for Use:
1. Sterile: **Single use only!**
2. Sterility not guaranteed if packaged has been opened or damaged. Inspect before use
3. Discard if package is damaged. Do not re-sterilize.
4. Notes on use: Please read all information carefully.

Important: These notes are not intended as a substitute for the equipment operating instructions. If in doubt, read the equipment instructions or ask the appropriate equipment representative for assistance.

Notes on Use:
Use aseptic technique when removing the Scalpel Blade from package.
2. Remove safety sticker from forward end of Scalpel and check electrode connection for secure fit.
3. Depress the silver button above the round receptacle and insert the round white connector at the end of the Scalpel into the round receptacle of USMI's Canady Plasma™ Coagulator (CPC) Argon 2 or Argon 4 clockwise until tight.
4. Insert the three (3) pronged plug end of the Scalpel into the receptacle of USMI's CPC Argon 2 or Argon 4.

Activation Modes: "CUT", "COAG", "HYBRID PLASMA CUT" AND "ARGON PLASMA COAGULATION".

1. To activate "**CUT**" mode, depress the top **(yellow)** button. The electrode should be fully exposed by sliding the gray middle knob backwards. The CPC Argon 2 or 4 will display **ZERO (0)** on the screen.
2. To activate "**COAG**" mode, depress the middle **(blue)** button. The electrode should be fully exposed by sliding the gray middle knob backwards. The CPC Argon 2 or Argon 4 will display **Zero (0)** on the screen.
3. To activate " **HYBRID PLASMA CUT**" mode press the bottom **(purple)** button to activate the argon gas flow, CPC Argon 2 or 4 will display the flow rate setting on the screen. Then depress the top **(yellow)** button to activate the "**Hybrid Plasma Cut Mode**". To switch back to standard cut mode press down on the purple button the the CPC will read **Zero (0)** on the screen. Afterwards press down on the yellow button to cut.
4. To activate "**ARGON PLASMA COAGULATION" (APC)** press bottom **(purple)** button to activate the argon gas flow, the CPC Argon 2 or 4 will display the flow setting on the screen. Then depress the middle **(blue) button** to activate the APC mode. To switch back to standard "**COAG**" press down on the purple button the CPC will read **ZERO (0)** on the screen. Afterwards press down on on the blue button to coagulate.

Indications for Use: The Hybrid Plasma Scalpel provides enhanced cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

Expiration Date: An expiration date is printed on the packaging of the probes. Do not use any probe beyond its expiration date.

Warning:
1. Do not use in presence of flammable anesthetics, disinfecting agents, or other combustible materials.
2. Do not fixed the plasma scalpel cord with metal instruments to surgical drapes. Activation of the plasma scalpel blade in contact with metal instruments may cause burns at the tissue or instrument interface.
3. Keep the hand control plasma scalpel in the holster when not in use. This will prevent an unnecessary contact with patient, surgical personnel or with fluids.
4. Do not attempt to coagulate vessels larger than 3mm in diameter.
5. Do not used for endometrial ablation. High risk for air/gas embolism inside the uterus .

Cautions:
1. Unusual request for increased power output settings should be question.
2. Plasma Scalpel should be kept away from sharp objects to prevent damage to insulation.
3. Do not used the plasma scalpel if you are unfamiliar with its operation in conjunction with USMI's Canady Plasma™ Electrosurgical Unit and Canady Plasma™ Coagulator.
4. Do not test the USMI Electrosurgical Generator with Canady Vieira Hybrid Plasma™ Scalpel by sparking the active electrode to the patient plate or other objects.
5. Before use always inspect the tip, the cord insulation and plasma scalpel integrity and condition. Do not used damaged plasma scalpel or cord.
6. Do not modify the plasma scalpel tip. Modification may have an effect on the performance of the plasma scalpel.

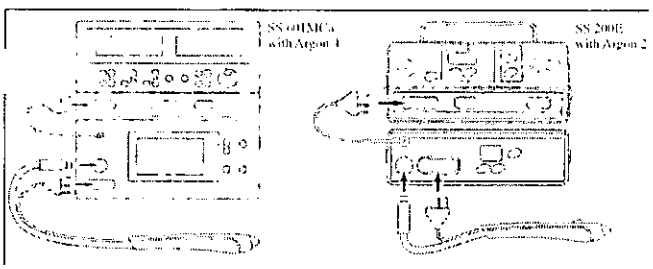
Recommended Settings for Open Surgery:
1. "**CUT**" mode, surgeon should set power settings similar to using other electrosurgical pencils for open surgery. Recommend not to exceed 50 watts in the cutting mode.
2. "**COAG**" mode, surgeon should set power settings similar to using other electrosurgical pencils for open surgery. Recommend not to exceed 60 watts in the coagulation mode.
3. "**ARGON PLASMA COAG**" (APC) surgeon should set power settings and flow rates similar to using other APC pencils for open surgery. Typically 20 to 60 watts at 2 to 5 liters/minute.

4. **"HYBRID PLASMA CUT"** surgeon should set power settings and flow rates typically at 20 to 80 watts @ 2 to 7 liters/ minute. Recommend not to exceed 120 watts.

Modification of the instrument by the user: US Medical Innovations, LLC warns explicitly against modifying the instrument, e.g. cutting off the probe tip. Any modification voids warranty and exempts US Medical Innovations from all liability.

After Use:

1. When the use of the plasma scalpel is finished, disconnect the scalpel by unplugging the plug from the receptacle of the "CPC" and disconnect the white round connector from the round receptacle by depressing down on the silver release button and turn counter-clockwise and pull straight out.
2. Dispose of the probe after use as required by hospital policy and applicable law.**"DO NOT RESTERILIZE"**



Distributed for:
US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33802

Canady Vieira Hybrid Plasma™ Scalpel

REF. AW-422552

CAUTION:
Federal law (USA) restricts this device to sale by or on the order of a physician.

Sterile Lot: XXXXXXXXX
Mfg. Lot: MM/DD/YY
Exp. Date: MM/DD/YY

STERILE EO

Patent Pending

Manufactured for:
US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803 USA

Probe: 3.0m
Handcontrol Penoil
Crayon de Commande Manuelle
Qty: 1

85°F 30°C
50°F 10°C

ref 30% ... 75%

LATEX

USMI™
US Medical Innovations

Canady Vieira Plasma ™
Ref.: AW-422552 / 3.0m
Sterile Lot: XXXXXXXX
Exp. Date: MM/DD/YY

Canady Vieira Plasma ™
Ref.: AW-422552 / 3.0m
Sterile Lot: XXXXXXXXX
Exp. Date: MM/DD/YY

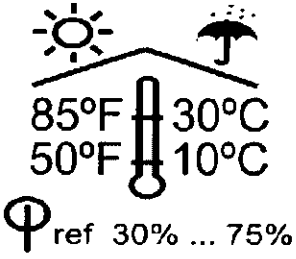
Canady Vieira Plasma ™
Ref.: AW-422552 / 3.0m
Sterile Lot: XXXXXXXXX
Exp. Date: MM/DD/YY

Canady Vieira Plasma ™
Ref.: AW-422552 / 3.0m
Sterile Lot: XXXXXXXXX
Exp. Date: MM/DD/YY

Canady Vieira Hybrid Plasma™ Scalpel

REF. AW-422552

Probe: 3.0m
Handcontrol Pencil
Crayon de Commande Manuelle
Qty: 5



LIFT here OPEN

CAUTION:
Federal law (USA) restricts this device to sale by or on the order of a physician.

STERILE EO

Sterile Lot: XXXXXXXXX
Mfg. Lot: MM/DD/YY
Exp. Date: MM/DD/YY

Patent Pending

Manufactured for:
US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803 USA

USMI™
US Medical Innovations

Canady Vieira Hybrid Plasma™ Scalpel

REF. AW-42252

CAUTION:
Federal law (USA) restricts this device to sale by or on the order of a physician.

STERILE EO

Sterile Lot: XXXXXXXXX
Mfg. Lot: MM/DD/YY
Exp. Date: MM/DD/YY

Patent Pending

Manufactured for:
US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803 USA

85°F 30°C
50°F 10°C
ref 30% ... 75%

USMI™
US Medical Innovations

Probe: 3.0m
Handcontrol Pencil
Crayon de Commande Manuelle
Qty: 5

LATEX

LIFT here OPEN

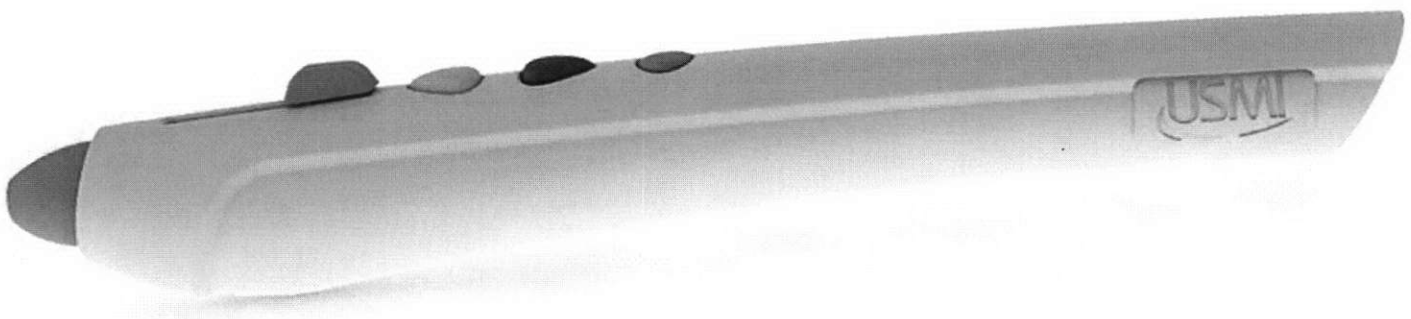
USMI

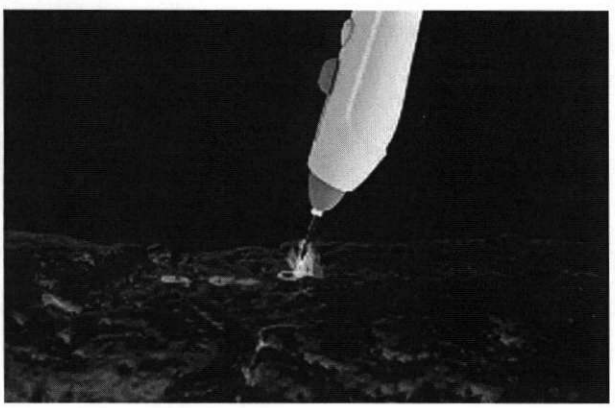
US Medical Innovations

Expertise. Ingenuity. Affordability.

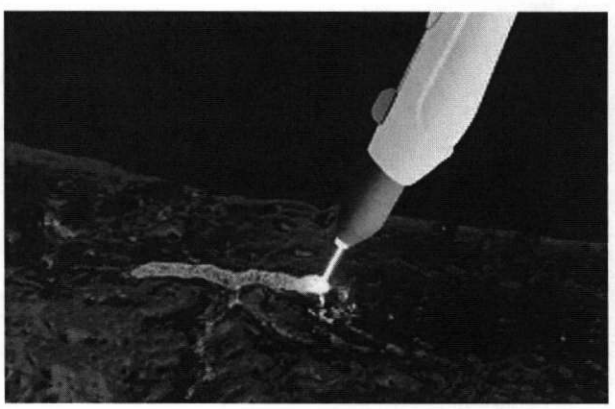
CANADY VIEIRA HYBRID PLASMA™ SCALPEL

Multi-functional electrosurgical handpiece that incorporates high frequency monopolar hybrid plasma cut with simultaneous coagulation of tissue.





Hybrid Plasma Cut



Argon Plasma Coagulation

US Medical Innovations
2940 Winter Lake Road • Lakeland, FL 33803 • Phone: 863.667.1609 • Fax: 863.667.1917 • usmedinnovations.com

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14. Sterilization & Shelf Life

14.1 Sterilization

The Canady Vieira Hybrid Plasma ™ Scalpel is sterilized using Ethylene Oxide (EtO). The finished device is packaged utilized a sealed envelope for sterilization (surgical grade material). One side of this envelope is made of polyethylene and the other made of surgical grade paper. The scalpel will be sterilized following finished device packaging. After the finished scalpel is inserted in the envelope, the primary package is sealed, and the final device is sterilized via Ethylene Oxide (EtO).

As part of this 510(k) submission 12 finished packaged devices, The Canady Vieira Hybrid Plasma ™ Scalpel, were tested to meet ISO 11135-1:2007-"Serilization of Health Care Products-Ethylene Oxide-Part 1" as part of the sterilization validation. The method that was used for sterilizing agent used was ethylene oxide 90%/CO^2 10%. The chamber's temperature was 50 ° C/+/- 10 ° at a pressure of -0, 30 Kgf/cm^2 +/- 0,1 at a relative humidity of 55 +/- 25%. The exposure time was 120 minutes. According to the report reference number 8618 all chemical indicators showed no microbial growth, the results were negative. The sterilization protocol and report is located in **Appendix 14A and 14B respectively**. A Sterility Assay report (NR.310612/003/004) was completed in accordance with USP 32/NF 27-2009 which is located in **Appendix 14C**.

14.2 Shelf Life

The Canady Vieira Hybrid Plasma ™ Scalpel U.S. Medical Innovations completed an accelerated aging on the product per ASTM F1980-"Accelerated Aging of Sterile barrier Systems for Medical Devices". The test that was performed was at a temperature of 60 ° C for 96 days to simulate a time period of 3 years. 5 finished device packages were tested for each time interval for seal integrity and tensile seal strength based on test report CETEA A035-2-I/11-Final, this report is located in **Appendix 14D and 14E.**

Pages 211 through 227 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Test Results

15. Biocompatibility

The probe and the electrode material (Tungsten) is patient contacting components, shown in Section 11 of this 510(k) notification. Biocompatibility testing was conducted on the Canady Vieira Hybrid Plasma™ Scalpel. Specifically, Blood Compatibility Assay, In-Vitro Cytotoxicity, Systemic Acute Toxicity, LAL Endotoxin, and Intracutaneous Biological testing. The detailed reports for each test are located in **Appendices 15**.

15.1 10993-4 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

The test evaluated the hemolytic properties of materials that are intended to be in contact with blood, was performed to validate the time to clot was observed. The results of this test showed that the results were satisfactory and did not vary the clotting time by more than 10%. The detailed report **NR304423/008/009** is located in **Appendix 15a**.

15.2 10993-5 _Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

The test evaluated the cytotoxicity potential and was conducted in conjunctive tissue cells of mice. The results of this test showed that the device samples that were provided did not present toxic effect to the cells. The detailed report **NR304423/009/009** is located in **Appendix 15b**.

15.3 USP 32/NF27-2009 Intracutaneous Biological Reactivity

The test evaluated macroscopic abnormalities in New Zealand albino mice potential. The results of this test showed that the device samples that were provided did not present abnormalities. The LAL testing was also conducted per this USP, and the concentration was below 0.5 EU/mL, per FDA medical device specifications. The detailed report **NR304423/011/011 NR310612/004/004** is located in **Appendix 15c and Appendix 15d, respectively**

15.4 10993-11 _Biological evaluation of medical devices -- Part 11: Tests for systemic acute toxicity

The test evaluated the systemic response during a short "in-vitro" observation period in a Swiss albino mouse. The results of this test showed that the device samples that were provided did not show a difference from the control group. The detailed report **NR304423/010/011** is located in **Appendix 15e**.

15.5 Summary

Biocompatibility testing was performed to validate the patient contacting material used for the Canady Vieira Hybrid Plasma™ Scalpel device. These tests were conducted in accordance with USP 32 or ISO 10993 and showed that the patient contacting material was nontoxic and did not cause an adverse reaction .

Pages 229 through 234 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Test Results

Software

This section of the 510(k) Submission is **not applicable**. The Canady Vieira Hybrid Plasma ™ Scalpel does not have any software or firmware associated with the board. Thus this is "dummy" board that is used jut to initiate a signal when the buttons are pushed.

Reason for Non-Applicability:

The Canady Vieira Hybrid Plasma™ Scalpel does not use software.

17. Electromagnetic Compatibility and Electrical Safety

The Canady Vieira Hybrid Plasma ™ Scalpel comply with IEC 60601-1 Standard, Electromedical equipment – Part 1 – General requirements for safety, NBR IEC 60601 – 2 – 2 Electromedical equipment –Part 2 – 2: Particular requirements for the safety of high frequency surgical equipment and was (b)(4) (b)(4) Both test passed the requirements according to Test Report Numbers AW002/2011 and AW003/2011 which is located in **Appendices 17a and 17b**.

Pages 238 through 306 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Test Results

(b)(6)

(b)(6)

Jerome Canady, M.D., CEO
Chief Science Officer
US Innovations,LLC
2940 Winter Lake Road
Lakeland, FL 33803

(b)(6)

(b)(6)

September 22, 2011

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SECTION 19 – PERFORMANCE TESTING – ANIMAL

Not applicable to this 510(k) submission.

SECTION 20 – PERFORMANCE TESTING – CLINICAL

Not applicable to this 510(k) submission.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name COYNE

Subject: 510(k) Number K113500

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement (4 PAGES)	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

Neonate/Newborn (Birth to 28 days)		✓
Infant (29 days -< 2 years old)		✓
Child (2 years -< 12 years old)		✓
Adolescent (12 years -< 18 years old)		✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*		✓

Regulation Number	Class*	Product Code
878.4400	II	GEI

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) REDB (Branch Code) 12/9/11 (Date)

Final Review: [signature] (Division Director) 12/6/11 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated
Third-Party Reviewed
K113500

Date: December 9, 2011
To: The Record
From: Laurence D. Coyne, Ph.D.

Office: ODE
Division: DSORD

Device Name: Canady Vieira Hybrid Plasma™ Scalpel

510(k) Holder: U.S. Medical Innovations, LLC
Jerome Canady, M.D.
2940 Winter Lake Road
Lakeland, Florida 33803

Third-Party: TÜV SÜD America, Inc.
1775 Old Highway 8
New Brighton, MN 55112-1891

Primary Reviewer:
Mr. Alexander Schapovalov
[PH] +49-89-5008-4309 mhs-fa@tuev-sued.de

Summary/Recommendation:
I recommend that the Canady Vieira Hybrid Plasma™ Scalpel be determined SUBSTANTIALLY EQUIVALENT to predicate devices. The sponsor has provided appropriate performance testing for this device in accordance with applicable standards for sterility validation, biocompatibility, electrical safety, electromagnetic compatibility, and ex vivo testing on pig liver samples, specifically for plasma length, tissue heating, diameter of eschar, and depth of injury. The sponsor has clearly benefited from previous extensive interactions with the agency on their most recent file, K100669. I have nothing to add that is not already stated within the third-party review memo.

Reviewer 12/9/11
Date

Division Concurrence 12/15/11
Date

7

THIRD PARTY REVIEW CHECKLIST

Is this 510(k) eligible for third party review?	Yes	No
Is the device on the list of eligible devices?* †	✓	
Can a determination of substantial equivalence be made without clinical data?†	✓	
Are you aware of the 510(k) holder being the subject of an Integrity Investigation? ‡		✓

*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring file to POS.
† If no, please bring submission to POS immediately.
‡ If yes, please bring submission to POS immediately.

A cover letter signed by the third party's official correspondent clearly identifying:	Yes	No
The purpose of the submission	✓	
The name and address of the third party	✓	
The name and address of the 510(k) holder	✓	
The purpose of the submission	✓	
The name of the device (trade name, common or usual name, and FDA classification name)	✓	
The third party's recommendation with respect to the substantial equivalence of the device	✓	
The date the third party first received the 510(k) from the 510(k) holder	✓	
A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	✓	
The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	✓	
A complete review of the 510(k) signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device.	✓	

A certification that:	Yes	No
The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	✓	
Statements made in the third party's review are true and accurate to the best knowledge of the third party	✓	
The third party's review is based on the 510(k) that it is submitting with the review	✓	
The third party understands that the submission to the government of false information is prohibited	✓	
Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review An Instruction Manual for Conducting Reviews of Premarket Notifications:		
Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)	✓	
Record of Deficiencies, if applicable	✓	
Indications for Use Form	✓	
510(k) Summary or Statement	✓	
510(k) Truthful and Accurate Statement	✓	
Third Party "Substantial Equivalence" (SE) Decision Making Documentation	✓	

If any of the above information is not included with the third party submission or is not adequate contact the third party and attempt to resolve the deficiency. Please include a memorandum to the record of the telephone call. When the information is received please revise this checklist or complete a new one.

COMMENTS:

Nichols, Karl *

From: Microsoft Exchange
To: 'mhs-fa@tuev-sued.de'
Sent: Friday, November 25, 2011 2:38 PM
Subject: Relayed: K113500- Acknowledgement Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'mhs-fa@tuev-sued.de'

Subject: K113500- Acknowledgement Letter

Sent by Microsoft Exchange Server 2007

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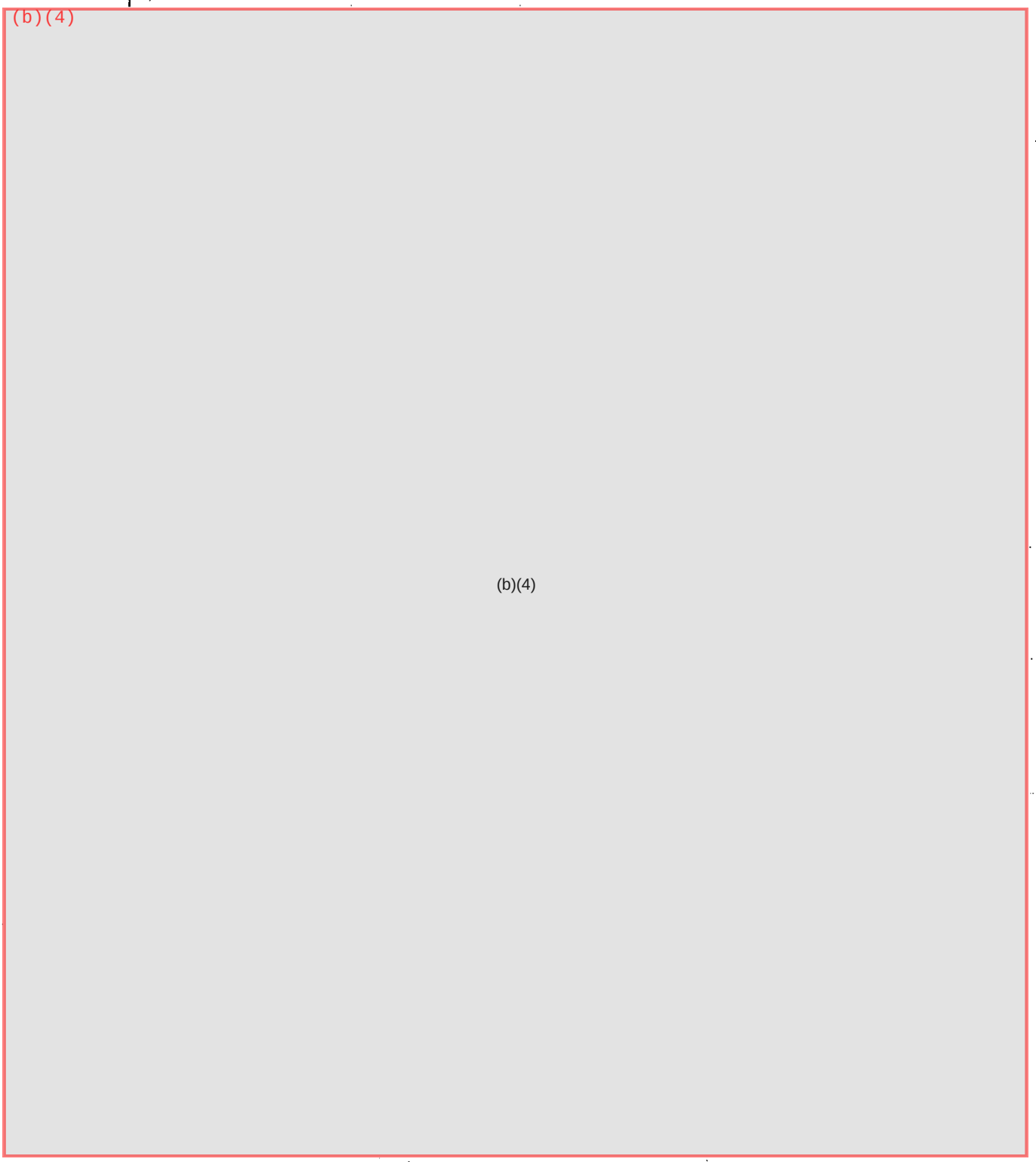
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS

(b)(4)



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.