DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

February 28, 2017

JAC-CELL MEDIC
% Mr. Jay Mansour
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K170105
Trade/Device Name: Jac-Cell Medic testers
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 22, 2016
Received: January 12, 2017

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170105

Device Name
JAC-CELL MEDIC TESTERS

Indications for Use *(Describe)*
The ATI-014A insulation and continuity testing system is a non-destructive, non-patient contacting, voltage insulation tester designed to test the insulation of electrosurgical instruments.
The ATI-021 has the same indications for use for insulation testing, but does not include continuity testing.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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K170105

510k Summary

As required by 21 CFR 807.92 (c)

1- Date summary prepared: February 27, 2017

2- Owner/Submitter/Sponsor/Applicant information:

JAC-CELL MEDIC
5764 Pare Street Tmr
Mont - Royal Quebec, CANADA H4P 2M2

3- Device information:

Common/usual/classification name: Insulation tester & Insulation and continuity tester

Device name: Jac-Cell Medic testers

FDA 3 letter code	GEI
FDA regulation number: 21 CFR	878.4400
Regulation medical specialty	General & Plastic Surgery
Review panel	General & Plastic Surgery
Class	2

4- Substantial equivalency is claimed against the following predicate device(s):

510k number	Trade or Proprietary or Model Name	Manufacturer
K020334	Insulation and continuity tester (ATI-014)	Jac-Cell Medic

5- Description of the device:

Device model name		Model number	
1	Insulation tester	1	ATI-021
2	Insulation and continuity tester	2	ATI-014A

The tester is a non-sterile multiple use handheld device operated by 9V battery. An embedded software (firmware) is used to program a microcontroller hardware platform, that interface the user's actions with visual and audible output signals.

The tester is used pre-operating room by nurses in hospitals, for the purpose of verifying the insulation (for ATI-021 and ATI-014A) and continuity (for ATI-014A) of electrosurgical instruments.

The tester is tested for functionality prior to each use, and is made out of the following components:

Component	ATI-021	ATI-014A
Foot pedal	yes	yes
End connector box	no	yes
Cable Male-Female (2)	yes	no
Adaptor Male-Male	no	yes
Adaptor Male- Alligator (1)	yes	no
Adaptor Male- Alligator (2)	no	yes
Test plate	yes	no
Brush test electrode	yes	yes
Hook test electrode	no	yes
Caring plastic case with foam	yes	yes

6- Intended use + indications for use

The ATI-014A insulation and continuity testing system is a non-destructive, non-patient contacting, voltage insulation tester designed to test the insulation of electrosurgical instruments. The ATI-021 has the same indications for use for insulation testing, but does not include continuity testing.

7- Basis for a determination of substantial equivalency:

(a) Indications for use:
The indication for use of ATI-014A and predicate ATI-014 are identical.
The indication for use of ATI-021 is covered by indications for use of predicate device ATI-014.

(b) Technological characteristics:
The technological characteristics are the same as the predicate device(s), as tabulated below:

Device		Predicate Device ATI-014	ATI-014A	ATI-021
Category/Parameter	**Specific Element of comparison**			
Indications for Use	**Identical**	Insulation/Continuity Testing	Insulation/Continuity Testing	Insulation Testing
Target population	**Identical**	Pre-operation nurses in Hospitals	Pre-operation nurses in Hospitals	Pre-operation nurses in Hospitals
Designation	**Identical**	Tester and Accessories	Tester and Accessories	Tester and Accessories
Material/Flammability rating	**Enclosure**	ABS Plastic/UL94-HB	ABS Plastic/UL94-V0 (flame retardant)	ABS Plastic / UL94-HB
Biocompatibility		Not Required, Non-Patient Contact	Not Required, Non-Patient Contact	Not Required, Non-Patient Contact
Energy Used	**Battery Powered**	Yes	Yes	Yes
	Rechargeable Battery	No	No	No
	Level	9V	9V	9V
	Average current consumption	30mA	20 mA	20mA
	Battery life (continous test)	30 hrs.	41 hrs.	41 hrs.
	Protection	Shortcircuit	Shortcircuit	Shortcircuit
	Battery level discharge warning	at 7V	at 7V	at 6.75V
Energy Delivered	1.5nF Capacitor discharge	not available	5.88 mJoules	5.88 mJoules
Performance		Voltage Insulation and Electrical Continuity Tester	Voltage Insulation and Electrical Continuity Tester	Voltage Insulation Tester

	Insulation testing section			**K170105**
	Working principle: High Voltage (HV) electrical discharge in area were insulation is broken	Yes	Yes	Yes
	High Level (for surface insulation testing) HV Output	2800 V	2800 V	2800 V
	Tolerance	+/-2.5%	+/-2.5%	+/-2.5%
	Low Level (for inside cable insulation testing) HV Output	1500V	1500V	not applicable
	Tolerance	+/-2.5%	+/-2.5%	not applicable
	Electrical continuity section			
	Working principle: Electrical resistance measuring	Yes	Yes	not applicable
	Continuity testing level	10 Ohms	10 Ohms	not applicable
	Tolerance	+/-20%	+/-10%	not applicable
	Shortcircuit testing level	150 Kohms	150 Kohms	not applicable
	Tolerance	+/-20%	+/-10%	not applicable
Compatibility with Environment and other devices		Non-RoHS	RoHS	RoHS
Usage		Pre-operating Room	Pre-operating Room	Pre-operating Room
Standard met	**Basic safety and Essential performance**	IEC60601-1:1988	ES60601-1:2005/(R02012 and A1:2012	ES60601-1:2005/(R02012 and A1:2012
	EMC/EMI Conformity	EN60601-1-2:2001	IEC60601-1-2:2007	IEC60601-1-2:2007
			FCC Part 15-Subpart B	FCC Part 15-Subpart B
			ICES-003	ICES-003
	Risk Analysis		ISO 14971:2007	ISO 14971:2007
Sterility		not applicable	not applicable	not applicable
Technical Information	**Manufacturing Technology**	Discrete Components	Surface Mount	Surface Mount
	Microcontroller embeded system	n/a	Yes	Yes
	Hand Held device	Yes	Yes	Yes
	Enclosure Model	1593-YGY	1553TT Bat	1553D Batt
	Dimensions	5.5"x2.6"x1"	6.5"x3.2"x1.4"	6"x3.5"x1.2"
	Weight	0.55 Lbs	0.57 Lbs	0.51 Lbs
	Tilt Stand	Yes	Yes	Yes
	Output Visual Signals			
	"Pass" for insulation testing	Green Light/Led	Green Light/Led	Green Light/Led
	"Fault" for insulation testing	Red Light/Led	Red Light/Led	Red Light/Led
	"Good" for electrical resistance testing	Green Light/Led	Green Light/Led	not applicable
	"Fault" for electrical resistance testing	Red Light/Led	Red Light/Led	not applicable
	"Battery Level" warning	Red Light/Led	Orange Light/Led	Orange Light/Led
	Output Audible Signals			
	On "Fault" detection	Yes	Yes	Yes

(c) Non clinical tests- brief discussion:

Bench testing confirms same performance to predicate device(s).

The bench tests of subject tester (ATI-014A) confirm it is substantially equivalent with the predicate one (ATI-014), from the point of view of testing principles (using the high voltage), input commands, output voltage level used for test, output signals and electrical resistance measurement for cables (i.e., both functions of insulation and electrical continuity testing).

The bench tests of subject tester (ATI-021) confirm that he is substantially equivalent with the predicate one (ATI-014), from the point of view of testing principles (using the high voltage), input commands, output voltage level used for test and output signals - for the function of insulation testing.

(d) Clinical tests- brief discussion:

Not applicable.

(e) Non clinical and clinical tests- conclusions drawn demonstrating that the device is as safe and as effective, and performs as well as or better than the predicate device(s):

Jac-Cell Medic testers perform as designed, in accordance with requirements. It is as safe and effective as the predicate device(s).