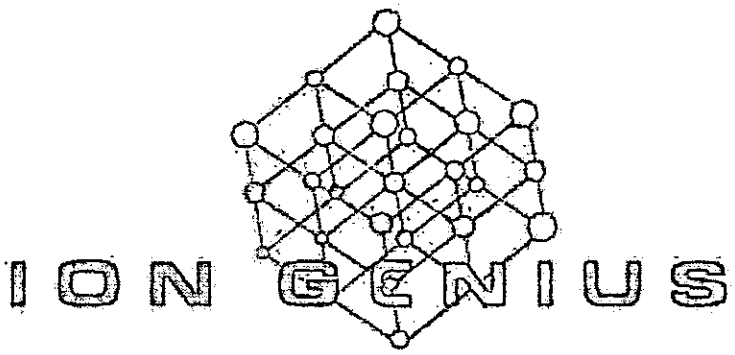

APR 2 8 2014

TRADITIONAL 510 K SUMMARY

K132179

1833 Kalakaua Ave, Suite 905 Honolulu, HI 96821
Phone: +1-866-25-YOUNG/808-395-0656 FAX: 877-26-YOUNG/808-395-0787
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510(k) Summary

Submitter's name:	Ion Genius, Inc.
Address:	Corporate Headquarters 1833 Kalakaua Ave Suite #905 Honolulu, HI 96815 Manufacturing Facility UV Innovations Ltd BIC 1 Innova Park Mollison Ave, Enfield, Middlesex, EN3 7XU, UK
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Company E-mail:	quality@iellios.com
Contact Person:	research@iellios.com
Contact Person Telephone:	1- 808 6461948
Date of Summary Is re-submitted:	February, 2014
FDA Establishment Registration No:	3003588228 (Ion Genius Inc)
Proprietary Name:	Arasys Genius
Common Name:	Muscle Stimulator for Conditioning
Regulation Description:	Powered Muscle Stimulator for Muscle Conditioning
Panel Code	89
Product Code:	NGX
Submission Type	510(k)
Regulation Number	890.5850
Device Class	II
Trade Name:	ARASYS GENIUS
Common Name:	Powered Muscle Stimulator for Muscle Conditioning
Classification Name:	Stimulator, muscle, powered, for muscle conditioning
Contact Person:	Xanya Sofra Weiss. Ph.D
Contact Person e-mail	research@iellios.com
Contact Person Telephone:	1- 808 6461948
Date that the Summary was prepared	July, 2013
Distributed by:	Ion Genius, INC Corporate Headquarters 1833 Kalakaua #905 Honolulu, HI 96815 Tel: 866-25-YOUNG tel:808-395-0656 Fax: 877-26-YOUNG

PREDICATE:

1.. Ion Magnum Genius
Contact Name: Xanya Sofra-Weiss. Ph.D
Ion Genius Inc / Ion Magnum LTD
Regulation No 890.5850
K 123158
Stimulator, muscle, powered, for muscle conditioning
Product Code: NGX

Device Description: The Arasys Genius has the exact same technological characteristics, the same number of channels and the exact same frequencies as the predicate,. Arasys Genius is made by UV Innovations by the same engineers and technicians that make the Ion Magnum Genius K123158. Arasys Genius has the exact same technology of the predicate, Ion Magnum Genius K123158 with the exceptions. The Arasys Genius is a muscle stimulator with six ports just like the predicate and one output that is the same for all ports just like the predicate. The unit is designed for healthy men & women to provide muscle conditioning. Arasys Genius stimulator provides selections of different programs through manual adjustment of the three different frequencies of the device, 90 Hz, 100 Hz, and 120 Hz. in an identical fashion as the predicate. The Arasys Genius maximum output current is 100 ma which is equivalent to the maximum output current of the predicate. The Arasys has a maximum output voltage of 200 volts which is equivalent to the maximum output voltage of the predicate. An LCD display shows the balance treatment time in the same fashion as it happens with the predicate. The output signal is biphasic, rectangular and based on a voltage and current regulated technology as it does in the predicate. The unit is easy and simple to use. The Arasys has an identical indication for use just like the predicate as it is intended for muscle conditioning to stimulate healthy muscles. The Arasys Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Arasys Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Arasys Genius is only offered under prescription given by a physician licensed in the state in which he or she practices.

NOTE 1: All channel;s outputs are isolated from each other. They have their own transformers and amplifiers which are independent from neighboring channels or outputs. The only common thing between the outputs is their connectors to the power supply, the start button, the programs button and the pulse button.
There is a transformer that translates energy received from the mains into micro currents. Hence there is an insulation of mains from circuitry. From Circuitry to output there is also insulation through the transformer. Therefore there is a double separation between mains and the human body.

This unit contains 32 self-adhesive electrodes that already have 510K clearance (K970426)

The Arasys Genius power source is 110V - 240 V AC Mains, 50-60 Hz which are identical to the predicate. The patient leakage current is 0.07 microamps under both the normal and fault conditions which are again are the exact same specs as the predicate. Channels are synchronous and are isolated by separate transformers the way the channels of the predicate are synchronous and isolated by separate

transformers. Arasys Genius has an automatic overload trip, just like the predicate but not an automatic no load trip just like the predicate that does not have a no load trip, therefore in terms of the overload trip features the Arasys Genius and the predicate are identical.. The Arasys Genius is also equivalent to the predicate in that it has an automatic shut off and patient override control for additional safety. Indicator displays include on and off status just like it does in the predicate. Arasys Genius is an IEC Class 1 device and an IEC 60417-5333, type BF applied part device exactly like the predicate.

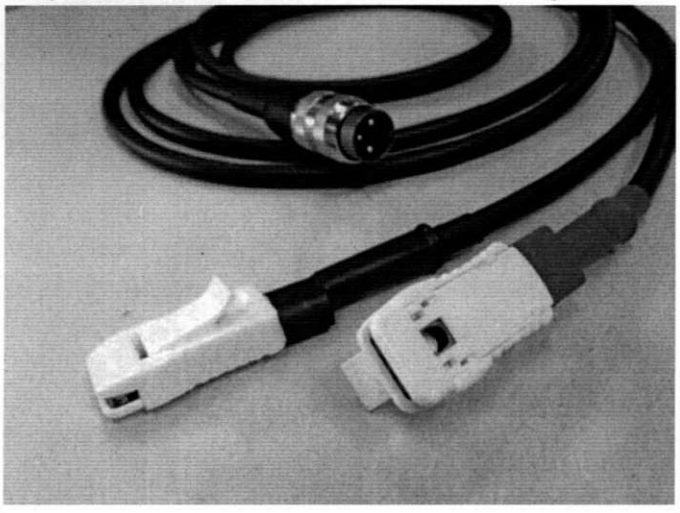
Proposed Conditions for Use: Both the Arasys Genius and the predicate, the Ion Magnum Genius K123158 are meant to be used in a professional setting like a spa, a medical spa or a professional office and to be operated by a professional and not by the patient.

In terms of how the device interacts with other devices. Neither the Arasys Genius nor the predicate the Ion Magnum Genius K123158 affect or are affected by other devices that may be in the same spa or office room.

In terms of how the Device interacts with the patient: Both Arasys Genius and Ion Magnum Genius K123158 interact in the same way with the patient. Both devices have cables that are screwed into the device. The other end of each cable has clips covered in plastic that snap into self adhesive pads. The self adhesive pads used both with the Arasys Genius and the predicate have been cleared (K970426) and therefore, they have been independently tested for biocompatibility, electrical performance, adhesive performance, stability, and reuse of such electrodes. These cleared self adhesive pads and they are applied onto the patient's muscles in the same fashion in both the Arasys Genius and the predicate.

The expected life of the device at least 10 to 15 years because inside the machine are microswitches that last for about 50,000 hours. Our company Ion Genius Inc offers life warranty on the Ion Magnum Genius. This means that we will repair any parts for free for as long as the customer owns the device.

The device enclosure has no protection against water because if the machine is completely closed up it may become overheated which will damage the device. There is a warning to keep the device away from liquids and water both on the device and the manual. The Device is for non-continuous operation.



The Arasys Genius is identical to the Ion Magnum Genius in that it has 6 3-pin din sockets that are located three on each side of the device THE DEVICE CABLES SCREW INTO THE DEVICE AND REMAIN SCREWED AT ALL TIMES. As seen in the pictures there are no exposed parts in the plastic covered cables so whoever is holding the cable is completely insulated and safe. ALL parts are touchproof The silver part that you see at the 3-pin din ending that goes into the device is plastic, so whoever holds it is completely insulated and safe. There are no exposed parts. Overall, the ARASYS GENIUS just like the Ion Magnum Genius lead wires screw into the device and remain screwed in at all times comply with IEC

60601-1:2005 Section 8.5.2.3 where connectors for electrical connections on a patient leads shall be constructed so that the said part cannot become connected to earth or possible hazardous voltage while the patient connection(s) contact the patient.

When the device is turned on, the pulses from the device are delivered to the patient's body to stimulate and condition the muscles. This procedure is identical in both the Arasys Genius and the predicate.

The Arasys Genius technological characteristics are identical to the predicate

1. Biphasic Rectangular Waveform
2. Synchronous channels
3. Maximum output voltage
4. Maximum output current
5. Identical frequencies
6. Pulse Duration
7. Pulse width
8. Maximum Phase Charge
9. Maximum Current Density
10. Channels' method of isolation by separate transformers
11. Identical Electrodes
12. Similar current leakage
13. Same accessories
14. Same electrodes that are cleared K970426
15. Identical number of channels
16. Equivalent dimensions, weight and Housing materials and construction
17. Identical method of line current isolation
18. Identical net charge

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
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 the device implanted?		X

Intended Use

Arasys Genius K 132179 is intended for muscle conditioning to stimulate healthy muscles. The Arasys Genius

is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Arasys Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Arasys Genius is only offered under prescription given by a physician licensed in the state in which he or she practices. The Arasys Genius is intended to be operated by a trained professional who is always present to monitor treatment.

COMPARISON OF INDICATIONS FOR USE OF ARASYS GENIUS AND PREDICATE K123158

Arasys Genius K 132179 is intended for muscle conditioning to stimulate healthy muscles. The Arasys Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Arasys Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Arasys Genius is only offered under prescription given by a physician licensed in the state in which he or she practices. The Arasys Genius is intended to be operated by a trained professional who is always present to monitor treatment. The Arasys Genius is intended to be operated by a trained professional who is always present to monitor treatment.	*Ion Magnum Geniu K123158 s is intended for muscle conditioning to stimulate healthy muscles. The Ion Magnum Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Ion Magnum Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Ion Magnum Genius is only offered under prescription given by a physician licensed in the state in which he or she practices.*

Substantial Equivalence based on the Indicatins of Use Statement: When compared to the predicated device, Ion Magnum Genius K123158 K123158 the Arasys Genius has the same intended use. Therefore, the Arasys Genius is substantially equivalent to the predicate marketed device Ion Magnum Genius K123158

COMPARISON OF DEVICE DESCRIPTION, SAFETY AND EFFECTIVENESS OF ARASYS GENIUS TO PREDICATE DEVICES:

Arasys Genius K132179 is a Muscle stimulator with six independent channels which electrical current can be regulated individually Biphasic rectangular impulses with electrical mean equal to zero. Maximum output current is 100 mA and maximum voltage output is 200 volts. The device gives 50V output at 500 Ohms overload and 200 volts at 10K Ohms overload. Maximum quantity of electricity per channel:40 µC Impulse width: 400 to 500 µsecs. The three Arasys Genius frequencies, 90 Hz, 100 and 120Hz are within the same range as the predicate. The electrical pulses generated by the Arasys Genius are transmitted to the muscles via self-adhesive electrodes, Axelgaard type electrodes electrodes which are cleared (510K K970426) The electrodes are identical to those used by the predicate.	**Ion Magnum Genius K123158" (K123158)** is a Muscle stimulator with six independent channels which electrical current can be regulated individually Biphasic rectangular impulses with electrical mean equal to zero. Maximum output current is 100 mA and maximum voltage output is 200 volts. The device gives 50V output at 500 Ohms overload and 200 volts at 10K Ohms overload. Maximum quantity of electricity per channel:40 µC Impulse width: 400 to 500 µsecs. The three Arasys Genius frequencies, 90 Hz, 100 and 120Hz are within the same range as the predicate. The electrical pulses generated by the Arasys Genius are transmitted to the muscles via self-adhesive electrodes, Axelgaard type electrodes electrodes (K970426)

Other equivalence aspects between Arasys Genius and the Predicate

Other equivalence aspects between Arasys Genius and the Predicate	1. Arasys Genius and the predicate devices are identical in terms of the thermal safety (there is no thermal energy for Arasys Genius or the predicate) 2. The chemical safety is equivalent (since this is applicable to neither the Arasys Genius nor the predicate) 3. Sterility is equivalent (since neither the Arasys Genius nor the predicate require sterilization or are supplied sterile.) 4. The Arasys Genius uses disposable pads that do not need sterilization that are equivalent to the pads of the predicate which also do not need sterilization because they are disposable. 5. Biocompatibility of the Arasys disposable pads is equivalent to those of the predicate and it is independently tested because the disposable pads are tested by the company that provides them and they are cleared (K970426). Biocompatibility is performed by the company from which these disposable pads are purchased (Axelgaard). Arasys uses disposable pads item no: SN2020 which are square 2" x 2" (5cm x 5cm) which have a 510K number K970426 and comply to ISO10993-5 Biological Evaluation of Medical Devices part 5 Test for in vitro cytotoxicity & ISO10993-10. The are made by Axelgaard Manufacturing Co. LtD, 520 Industrial Way Fallbrook California 92028, USA which has a Certificate of Registration Quality Management System – ISO 13485:2003 and holds certificate no FM 40363 and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope: The design and development, manufacture and distribution of hydrogel and non-invasive electrodes: Effective date 03/11/2012 – Expiry Date: 03/12/2015.)..

	6. The cables carrying the impulses to the pads and the connectors are both designed to insulate the client and operator from inadvertent contact with the relatively weak electrical impulses. Should the connectors be dislodged in use, for instance, by the client changing position during treatment, the insulation will ensure no direct contact with the skin will take place. The Arasys cables remain screwed on and attached to the device as are the cables of the predicate devices. 7. Proposed Conditions for Use: Both the Arasys Genius and the predicate, the Ion Magnum Genius K123158 are meant to be used in a professional setting like a spa, a medical spa or a professional office and to be operated by a professional and not by the patient.

OUTPUT SPECIFICATIONS COMPARING ARASYS GENIUS WITH THE PREDICATE DEVICES

	ARASYS GENIUS K132179	Ion Magnum Genius K123158	Equivalent
Waveform	Biphasic	Biphasic	Equivalent
Synchronous or alternating channels	synchronous	synchronous	Equivalent
Dimension of Device	15.5 inches length 4,5 height 7.5 width	15.5 inches length 8,5 height 7.5 width	Equivalent
Weight of the Device Weight of Accessories	8 pounds 4.7 pounds	8 pounds 4.7 pounds	Equivalent Equivalent
Indicator Display Low Battery Voltage Current Level	Yes N/A Yes	Yes N/A Yes	Equivalent
Shape	Rectangular	Rectangular	Equivalent
Max Output Voltage	50V @ 500 Ω	50V @ 500 Ω	Equivalent
	200 V @10k Ω	200 V @10k Ω	Equivalent
Max Output Current	100 ma at 500 Ohms	100 ma at 500 Ohms	Equivalent
Frequency (Hz) for Muscle Conditioning	90 Hz 100 Hz 120Hz	90Hz 100 Hz 120Hz	Equivalent

Pulse Duration	416 - 500 µsec	416 - 500 µsec	Equivalent
Pulse Width	416 - 500 µsec	416 - 500 µsec	Equivalent
Maximum Phase Charge	50 µC @ 500 Ω at 90 and 100 Hz 40 µC @ 500 Ω at 120 Hz	50 µC @ 500 Ω at 90 and 100 Hz 40 µC @ 500 Ω at 120 Hz	Equivalent
Maximum Current Density (mA/cm2)	4 mA/cm2	4 mA/cm2	Equivalent
Maximum Power Density (W/Cm2)	0.0012 W/cm^2	0.0012 W/cm^2	Equivalent
Current or Voltage Driven	Voltage Driven	Current Driven Voltage	Equivalent
Symmetrical Phases of Waveform	Yes	Yes	Equivalent
Regulated Current/ voltage	Regulated Voltage	Regulated Voltage	Equivalent
Number of Channels	6	6	Equivalent
Method of Channel Isolation	Channels are isolated by separated transformers	Channels are isolated by separated transformers	Equivalent
Self Adhesive Electrodes Axelgaard Tyoe K 970426	identical	Identical	Equivalent

Cables that screw into the device	identical	identical	Equivalent
Current Leakage	0.07 µA	0.07 µA	Equivalent
Net Charge	10,000 microcoulombs at 500 Ohms 4,000 microcoulombs at 2K Ohms 2,500 microcoulombs at 10K Ohms	10,000 microcoulombs at 500 Ohms 4,000 microcoulombs at 2K Ohms 2,500 microcoulombs at 10K Ohms	Equivalent
Method of Line Current Isolation	Separate Transformers.	Separate Transformers	Equivalent
Housing Material and Construction	Metal Enclosure	Metal Enclosure	Equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 28, 2014

Ion Genius, Inc.
Xanya Sofra-Weiss, Ph.D.
Director of Research and Training
1833 Kalakaua Ave, Suite #905
Honolulu, HI 96821

Re: K132179
Trade/Device Name: Arasys Genius
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: March 17, 2014
Received: March 27, 2014

Dear Dr. Xanya Sofra-Weiss:

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" (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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Peña-S

Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine 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 on last page.

510(k) Number *(if known)*
K132179

Device Name
Arasys Genius

Indications for Use *(Describe)*
Arasys Genius is intended for muscle conditioning to stimulate healthy muscles. The Arasys Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Arasys Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Arasys Genius is only offered under prescription given by a physician licensed in the state in which he or she practices. The Arasys Genius is intended to be operated by a trained professional who is always present to monitor treatment.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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