11/16/2020

Vision Quest Industries Inc.
Mohamed Ouerghi
Director of QA/RA
1390 Decision Street, Suite A
Vista, California 92081

Re: K202490
Trade/Device Name: Avid CT2 Neuromuscular and Interferential Stimulation System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, LIH
Dated: October 2, 2020
Received: October 5, 2020

Dear Mohamed Ouerghi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaorui Tang, Ph.D.
Acting Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202490

Device Name

Avid CT2, Neuromuscular and Interferential Stimulation System, Model AV-CT20A

Indications for Use *(Describe)*

lnterferential Stimulation can be used in the following applications:
• Symptomatic relief of post-surgical and/or post traumatic acute pain
• Symptomatic relief of chronic intractable pain
• Relaxation of muscle spasms
• Maintain or increase range of motion
• Increase local blood circulation

Neuromuscular Stimulation can be used in the following applications:
• Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis
• Prevention or retardation of disuse atrophy
• Muscle-re-education

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.

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510(k) SUMMARY

510(k) Owner:	Vision Quest Industries, Inc. 18011 Mitchell South, Irvine, CA, 92614
Contact:	Mohamed Ouerghi Director of QA/RA Vision Quest Industries, Inc. Phone 760-477-8201 Mobile 760-691-0168 Fax 760-727-5950 mouerghi@vqorthocare.com
Date Summary Prepared:	8/26/2020
Proprietary Name:	Avid CT2 Neuromuscular and Interferential Stimulation System, Model AV-CT20A
Device Name and Classification:	Neuromuscular and Interferential Stimulator, Class II, 21 CFR 882.5890, Product Code LIH and 21CFR 890.5850, Product Code IPF
Predicate Devices:	Surgi Stim/T.E.A.R. Tech by Vision Quest Industries, Inc. K982388 and Avid IF2 by Vision Quest Industries, Inc.K183692
Device Description:	The Avid CT2, Model AV-CT20A is a combination therapy device. Like its predicate Avid IF2, it is an Interferential Stimulator that produces a low electrical current that is transmitted via lead wires to electrodes placed on the skin in the area predetermined by a clinician. Operating parameters can be adjusted throughout their range by a trained clinician but the end-user is limited to protocol selection and amplitude. The user interface consists of an LCD display and a keypad. The primary difference between the two devices is the addition of user-adjustable parameters that allow the existing interferential waveform to turn on and off within a small, preselected range to provide necessary control for neuromuscular stimulation. This same method of gating the interferential on and off was used in VQ's previous Surgi Stim stimulator.

Statement of Intended Use: The Avid CT2 Neuromuscular and Interferential Stimulator**,** Model AV-CT20A, is indicated for use in the following applications:

Interferential Stimulation can be used in the following applications:

- Symptomatic relief of post-surgical and/or post traumatic acute pain
- Symptomatic relief of chronic intractable pain
- Relaxation of muscle spasms
- Maintain or increase range of motion
- Increase local blood circulation

Neuromuscular Stimulation can be used in the following applications:

- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis
- Prevention or retardation of disuse atrophy
- Muscle-re-education

Substantial Equivalence

The Avid CT2 is a minor product enhancement to the Avid IF2. The primary difference between the two devices is the addition of user-adjustable parameters that allow the existing interferential waveform to turn on and off within a small, preselected range to provide necessary control for neuromuscular stimulation. This same method of gating the interferential on and off was used in VQ's previous Surgi Stim stimulator.

The Avid CT2 is equivalent to the Avid IF2 in all areas except these new user-adjustable parameters. For those parameters we are substantially equivalent to VQ's Surgi Stim stimulator.**.**

Indications for Use

The Avid CT2 has the same indications for use as the Avid IF2 when these are used in IF mode. The Avid CT2 has the additional indications for use as allowed by neuromuscular stimulators.

Device Functionality Equivalency

- Like the predicate devices, the new device uses a microcontroller and LCD display to create a user friendly interface.
- The Avid IF2 and CT2 Stimulator is self-contained and includes two non-removable, rechargeable lithium ion batteries and an external power supply like the predicates.
- The Avid IF2 and CT2 Stimulator also contain a single output jack for both output channels, and a user interface consisting of a touchscreen LCD for improved user experience. The electrodes used for stimulation are the same used with the predicates. The lead wires are of proprietary design.
- The user is able to select presets on the device for the desired treatment and waveform output based upon prescriptions from the treating clinician. This is accomplished by displayed menu items and selection through the device interface. If desired, the user will be able to upload data stored on the device to Vision Quest Industries, Inc. (via wired interface or wirelessly). The device has the ability to move from preset to preset without patient interaction. This allows for easy use of physician prescribed protocols.

Device Characteristics and Output Specifications Equivalency

The Avid IF2 only has the IF mode whereas the Avid CT2 has an additional neuromuscular mode. The second predicate device from Vision Quest Industries, Inc. has three modes of stimulation: High Volt Pulsed Current (HVPC), Interferential (IF), and a Neuromuscular Electrical Stimulation (NMES) mode.

The tables below compare the Avid CT2 to the two predicate devices.

Device Characteristics Comparison

510(k) Number Device Name **Manufacturer**	K982388 Surgi Stim /T.E.A.R. Tech **Vision Quest Industries, Inc.**	K183692 Avid IF2 **Vision Quest Industries, Inc.**	Unassigned Avid CT2 **Vision Quest Industries, Inc.**
Power Source	2 battery packs consisting of 4 'AA' alkaline cells each or external power supply	2 internal, non-removable, rechargeable Lithium-ion batteries or external power supply	2 internal, non-removable, rechargeable Lithium-ion batteries or external power supply
-Method of Line Current Isolation	Use of UL2601-1 approved external power supply	Use of UL2601-1 approved external power supply	Use of UL2601-1 approved external power supply
-Patient Leakage Current			
-Normal Condition (μA)	<500	<500	<500
-Single fault condition (μA)	<500	<500	<500
No. of Output Modes	3 (IF, HVPC, NMES)	4 (IF)	1 (IF, NMES)
No. of Output Channels	IF Mode – 2 IF Mode – 1 NMES Mode- 2 NMES Mode -1 HVPC Mode - 1	IF Mode – 2 IF Mode – 1	IF Mode – 2 IF Mode – 1 NMES Mode – 2 NMES Mode -1
Synchronous or Alternating	IF – Synchronous NMES – Synchronous HVPC – Synchr. Or Alt.	IF – Synchronous	IF – Synchronous NMES – Synchronous
Method of Channel Isolation	IF - Transformer coupled NMES - Transformer coupled HVPC – N/A	IF – Transformer coupled	IF – Transformer coupled NMES - Transformer coupled
Reciprocal	IF - No NMES - No HVPC - Yes	IF – No	IF – No NMES - No
Regulated Current or Regulated Voltage	IF – Regulated voltage NMES – Regulated voltage HVPC – Regulated voltage	IF – Regulated voltage	IF – Regulated voltage NMES– Regulated voltage
Software/Firmware/ Microprocessor Control	Microprocessor Control	Microprocessor Control	Microprocessor Control
Software Provided	Yes-Embedded Firmware	Yes- Embedded Firmware	Yes- Embedded Firmware
Automatic Overload Trip	No	Yes	Yes
Automatic No-Load Trip	No	Yes (w/override option)	Yes (w/override option)
Automatic Shut Off	Yes	Yes	Yes
Patient Override Control	Yes	Yes	Yes
Indicator Display:			
Unit Functioning	Yes	Yes	Yes
On/Off Status	Yes	Yes	Yes
Low Battery	Yes	Yes	Yes
Voltage/Current Level	4.4V	5.75V	6.0V
Other	LCD panel displays all parameter settings.	LCD panel displays all parameter settings.	LCD panel displays all parameter settings.
Constant Current	IF- No	IF – No	IF – No

Device Characteristics Comparison

510(k) Number Device Name **Manufacturer**	K982388 Surgi Stim /T.E.A.R. Tech **Vision Quest Industries, Inc.**	K183692 Avid IF2 **Vision Quest Industries, Inc.**	Unassigned Avid CT2 **Vision Quest Industries, Inc.**
	NMES- No HVPC- No	NMES – No	NMES – No
Constant Voltage	IF- Yes NMES- Yes HVPC- Yes	IF – Yes	IF – Yes NMES – Yes
Timer Range (minutes)			
Timer Settings	10 min to 8 hours or continuous	1 min to 24 hours or continuous	1 min to 24 hours or continuous
Compliance with voluntary Standards	Standards-AAMI/ANSI NS4 1986	NA	NA
Compliance with EN60601-1 (Safety)	Not Tested	Yes	Yes
Compliance with IEC60601-1-2 (EMC)	Not Tested	Yes	Yes
Compliance with 21 CFR 898 (Mandatory 05/09/02)	NA	Yes	Yes
Weight (with batteries)	10.6 oz.	6.8 oz.	6.8 oz.
Dimensions (inches)	5.7 x 3.0 x 1.5	4.9 x 2.85 x 1.0	4.9 x 2.85 x 1.0
Housing Materials and Construction	Molded ABS/PC plastic housing	Molded ABS/PC plastic housing	Molded ABS/PC plastic housing

Technical Explanations:

The following device performance description/comparison to predicate devices are provided in accordance with the FDA document "Guidance Document for Powered Muscle Stimulator 510(k)s" Attachment II section 3, issued on June 9, 1999.

The above document also requires some explanations of calculations and modulations – these are provided below.

Interference Pattern
The interference pattern is created using two different frequencies. When the four electrode stimulation is selected two separate frequencies are provided on the two electrode pairs.

Interference occurs at the patient. When two electrodes stimulation is selected the two frequencies are combined inside the device and the interference pattern is delivered via the one electrode pair.

Current Density
Current density is calculated using 2 different electrode sizes. A 2" round electrode equal to 20.27 sq. cm and a 2" x 1.25" rectangular electrode is equal to 16.13 sq. cm. This second electrode is used in the Limited mode output where amplitude is limited to 60% of full power.

In the IF mode current density is the pulsed current over the electrode area. Each phase is 50% of the pulse thus the average is given as half.

Power Density
Power density is calculated in a similar manner to current density except that the peak phase power density is the max voltage times the max current.

Maximum Phase Charge

In the IF mode, charge (Q) can be calculated as follows:

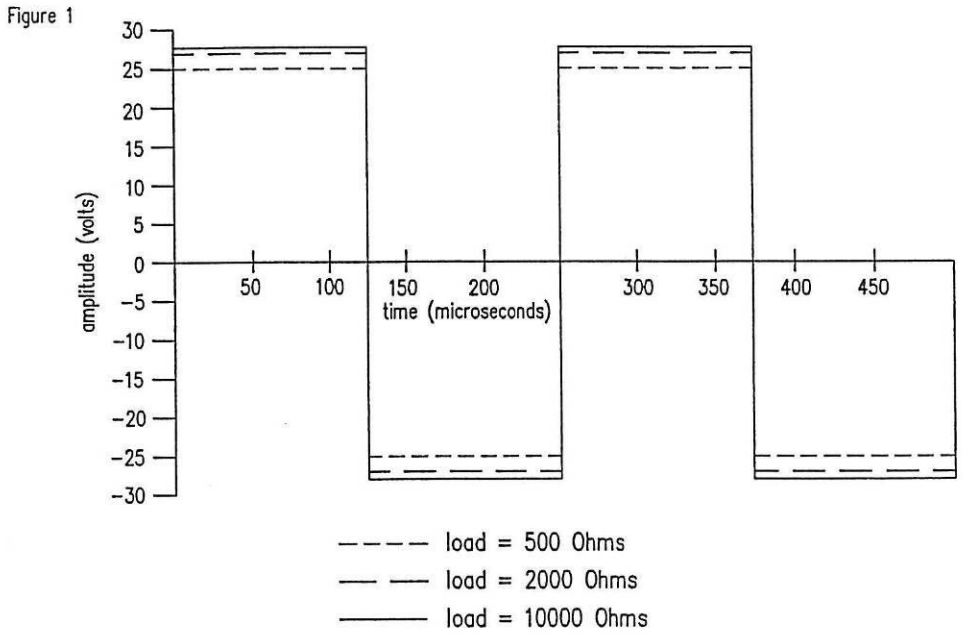
(Peak voltage/load) X duration of pulse

Waveform Drawings Explanations

The waveform drawings are provided in accordance with the "Guidance Document for Powered Muscle Stimulator 510(k) s".

Waveform Drawing 1

Figure 1 This drawing shows the output waveform in the IF stimulation mode. Waveforms are given with purely resistive loads of 500 Ohms, 2000 Ohms, and 10,000 Ohms as required.



Waveform Drawing 2

Figure 1 Modality = IF Mode = 6/6

This drawing represents the frequency of a series of pulses when the device is in the IF mode with frequency modulation. The modulation parameters are six second ramping between the preset frequencies.

When the device is turned on pulses begin at 60% of the user selected frequency (4000Hz plus beat frequency) over a six second period, ramp up to 160% of the selected frequency. Over the next six second period the frequency ramps down to 60% of the setting again and the cycle starts over.

Figure 2 Modality = IF Mode = 6|6

This drawing represent the frequency of a series of pulses when the device is in the IF mode with frequency modulation. The modulation parameters are six seconds, abruptly changing between the preset frequencies.

When the device is turned on pulses begin at 60% of the user selected frequency (4000Hz plus beat frequency) over a six second period, instantly change to 160% of the selected frequency for six seconds. The frequency then instantly decreases down to 60% of the setting again and the cycle starts over.

Waveform Drawing 2

Figure 1

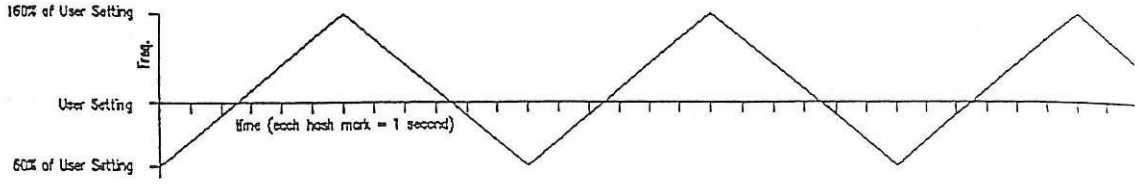
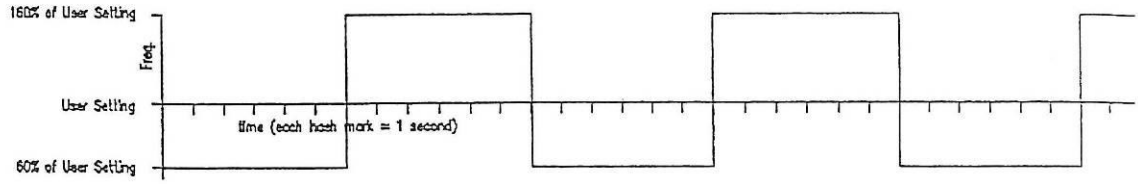


Figure 2



Waveform Description

The waveforms from the Avid CT2 are the same as the predicate devices. A description of the waveforms is provided below in table format allowing comparison of measured values. For a visual comparison, scope traces of all three devices are also provided below.

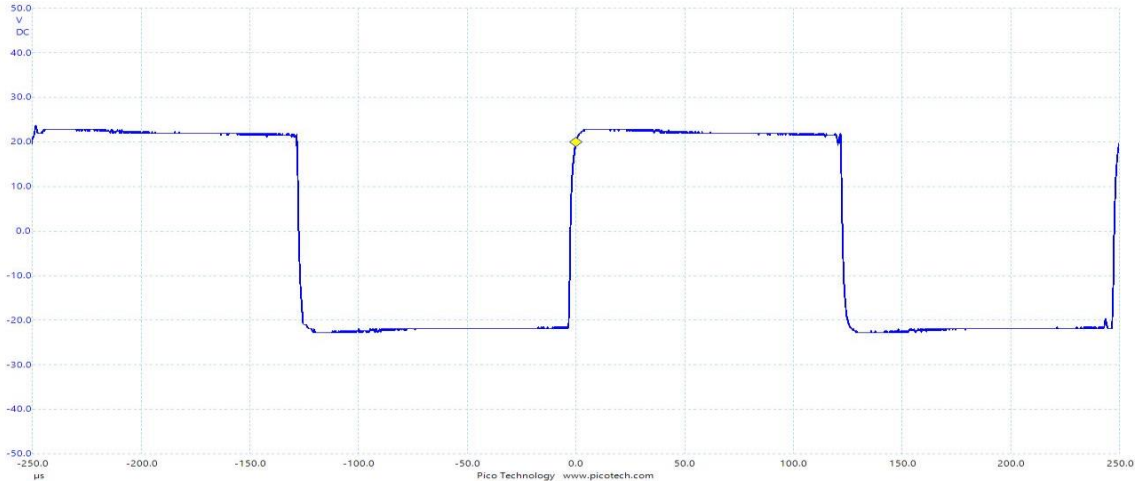
Note that the scope traces of all three devices show a slight improvement with each generation; cleaner wave forms and less voltage variation over load.

Output Specifications Comparison

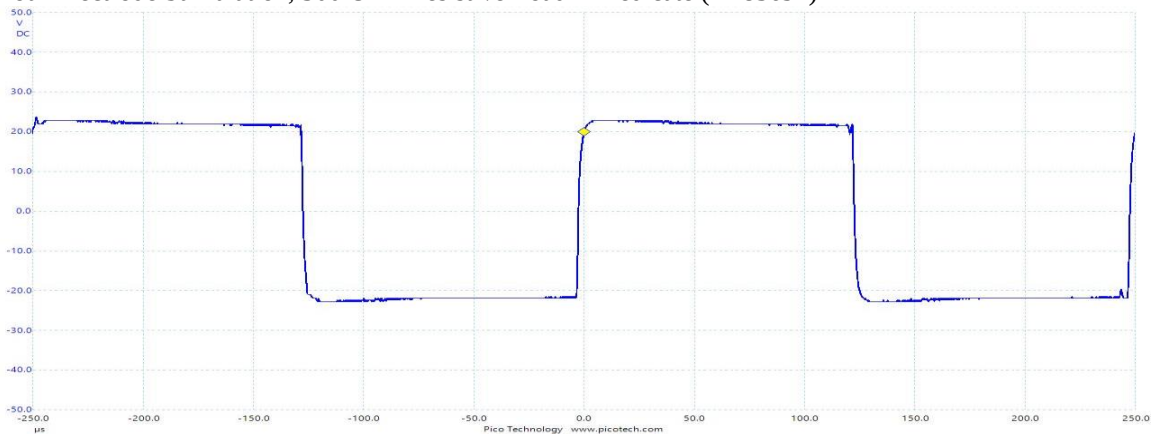
510(k) Number Device Name	K982388 Surgi Stim /T.E.A.R. Tech	K183692 Avid IF2	Unassigned Avid CT2
Waveform	IF- Sym. Biphasic NMES–Sym. Biphasic HVPC- Twin peak pulsed monophasic	IF – Sym. Biphasic	IF – Sym. Biphasic NMES–Sym. Biphasic
Max. Output Current (500 Ohm Load)	IF Mode – 50mA ±10% NMES Mode- 50mA ±10% HVPC- .66A ±10%	IF Mode – 50mA+/- 10%	IF Mode – 50mA+/- 10% NMES Mode- 50mA ±10%
Max. Output Voltage (500 Ohm Load)	IF- 25V ± 10% NMES- 25V ±10% HVPC 330V ±10%	IF – 25V +/- 10%	IF – 25V +/- 10% NMES – 25V +/- 10%
Shape	IF- Square or rectangular NMES- Square or rectangular HVPC- Dual exponential spike	IF – Square or rectangular	IF – Square or rectangular NMES – Square or rectangular
Symmetry	IF- Symmetrical NMES- Symmetrical HVPC - No	IF – Symmetrical	IF – Symmetrical NMES – Symmetrical
Net Phase Charge	IF - 0µC NMES – 0µC HVPC- 8.25µC	IF – 0µC	IF – 0µC NMES – 0µC
Peak Phase Current (500 Ohm)	IF – 50mA NMES – 50mA HVPC – 0.66A	IF – 50mA	IF – 50mA NMES – 50mA
Peak Phase Voltage (500 Ohm)	IF-25V NMES – 25V HVPC-330V	IF – 25V	IF – 25V NMES – 25V
Phase Rise Time (500 Ohm, max.width)	IF - < 2µS NMES- <2µS HVPC- <1µS	IF - < 2µS	IF - < 2µS NMES - < 2µS
Phase Decay Time (500 Ohm, max. width)	IF- < 2µS NMES- <2µS HVPC- 27µS	IF- < 2µS	IF- < 2µS NMES- < 2µS
Phase Duration Range (at 50% max. width)	IF - 7µS – 125µS NMES - 7µS – 125µS HVPC- 5µS	IF - 7µS – 125µS	IF - 7µS – 125µS NMES - 7µS – 125µS
Interphase Interval	IF – 0µS NMES – 0µS HVPC – 100 - 300µS	IF – 0µS	IF – 0µS NMES – 0µS
Frequency Range	IF- 4000 Hz – 4240 Hz NMES – 4000Hz - 4240 Hz HVPC – 1-200 Hz	IF- 4000 Hz – 4240 Hz	IF- 4000 Hz – 4240 Hz NMES- 4000 Hz – 4240 Hz
Interference Pattern	IF – Yes NMES - Yes HVPC – No	IF – Yes	IF – Yes NMES – Yes
Beat Frequencies	IF- 1-240 Hz NMES – 1-240Hz HVPC – NA	IF- 1-240 Hz	IF- 1-240 Hz NMES- 1-240 Hz
Burst Mode	No	No	No
Current Density			
Peak (per sq. cm) (500 Ohm Load)	IF – 2.47mA NMES – 2.47mA HVPC – 65.1mA	IF – 2.47mA	IF – 2.47mA NMES – 2.47mA
Ave. (per sq. cm) (500 Ohm Load)	IF – 1.235mA NMES – 1.235mA HVPC – 0.13mA	IF – 1.235mA	IF – 1.235mA NMES – 1.235mA

Output Specifications Comparison			
510(k) Number Device Name	K982388 Surgi Stim /T.E.A.R. Tech	K183692 Avid IF2	Unassigned Avid CT2
Power Density			
Peak (per sq. cm) (500 Ohm Load)	IF – 61.7mW NMES – 61.7mW HVPC – 10.7 W	IF – 61.7mW	IF – 61.7mW NMES – 61.7mW
Ave. (per sq. cm) (500 Ohm Load)	IF – 30.85mW NMES – 30.85mW HVPC – 21.4 mW	IF – 30.85mW	IF – 30.85mW NMES – 30.85mW
Max. Phase Charge			
500 Ohms	IF- 6.25µC NMES – 6.25 µC HVPC- 9.9 µC	IF- 6.25µC	IF- 6.25µC NMES- 6.25µC
2K Ohms	IF- 1.56 µC NMES – 1.56 µC HVPC- 1.65 µC	IF- 1.56 µC	IF- 1.56 µC NMES- 1.56 µC
10K Ohms	IF- 0.33 µC NMES – 0.33 µC HVPC- 0.33 µC	IF- 0.33 µC	IF- 0.33 µC NMES- 0.33 µC

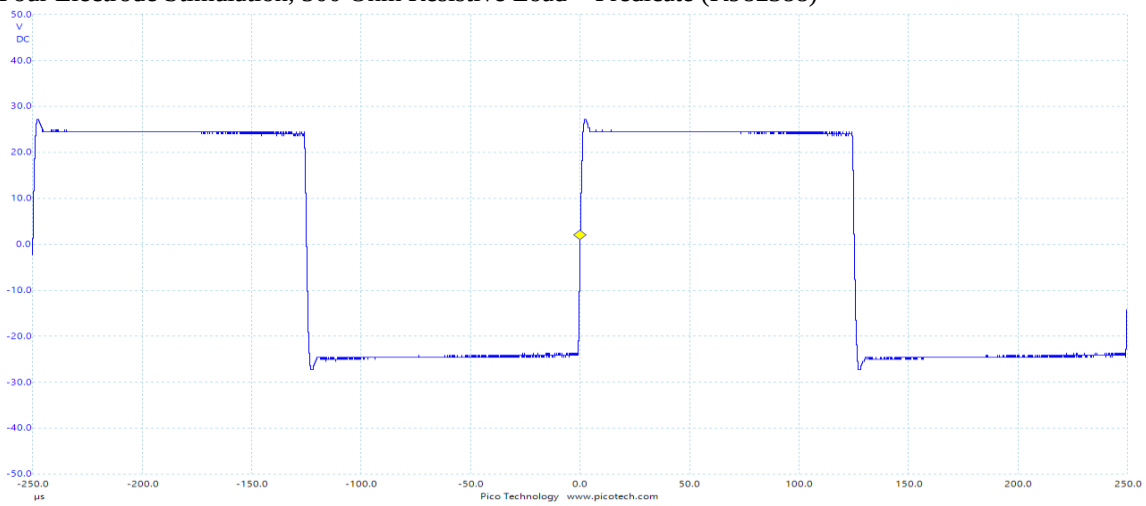
Four Electrode Stimulation, 500 Ohm Resistive Load – Avid CT2



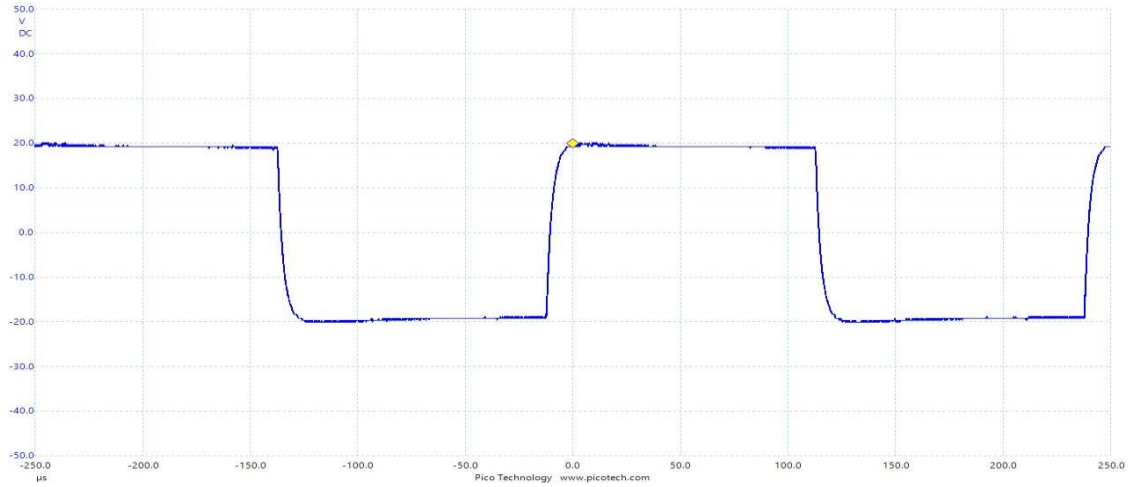
Four Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K183692)



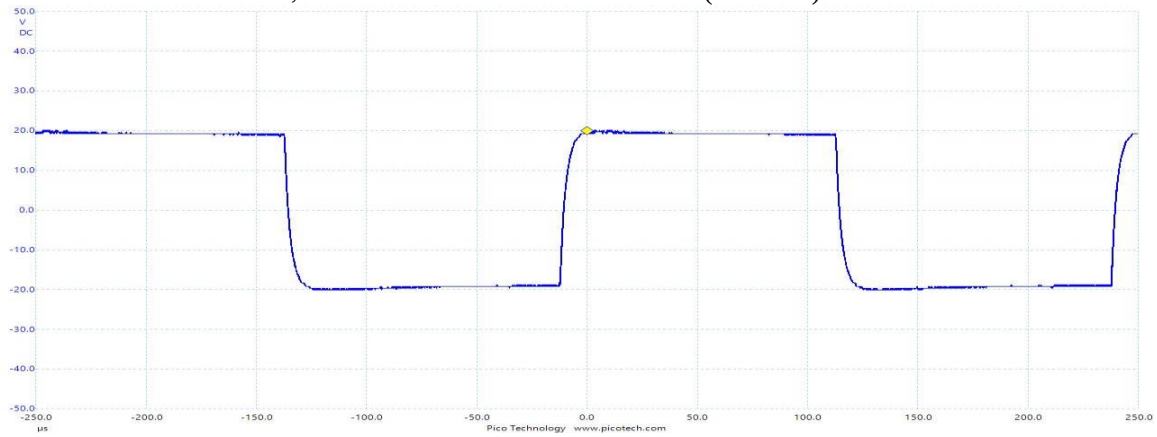
Four Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K982388)



Four Electrode Stimulation, 200 Ohm Resistive Load – Avid CT2



Four Electrode Stimulation, 200 Ohm Resistive Load – Predicate (K183692)



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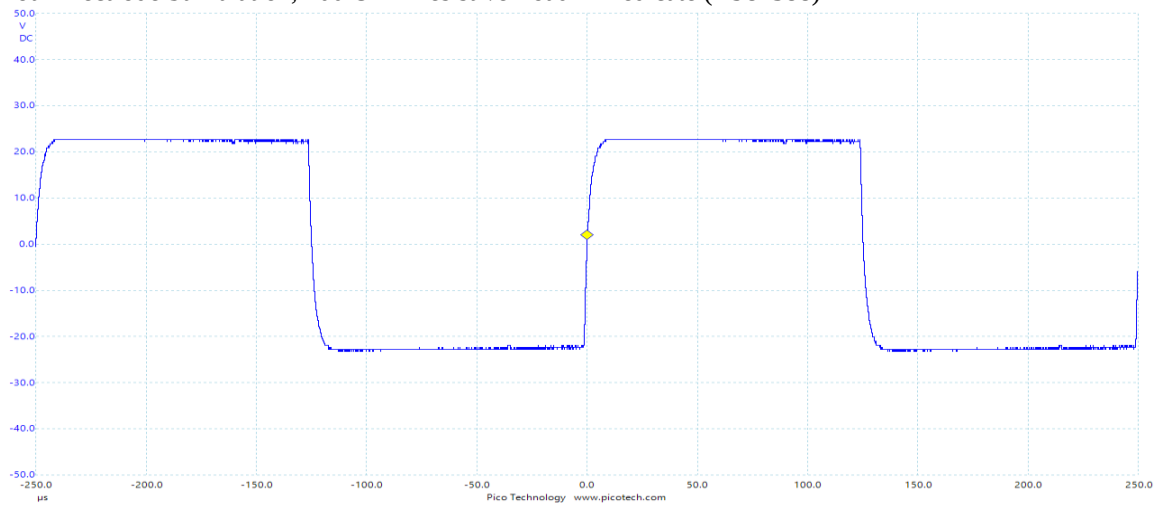
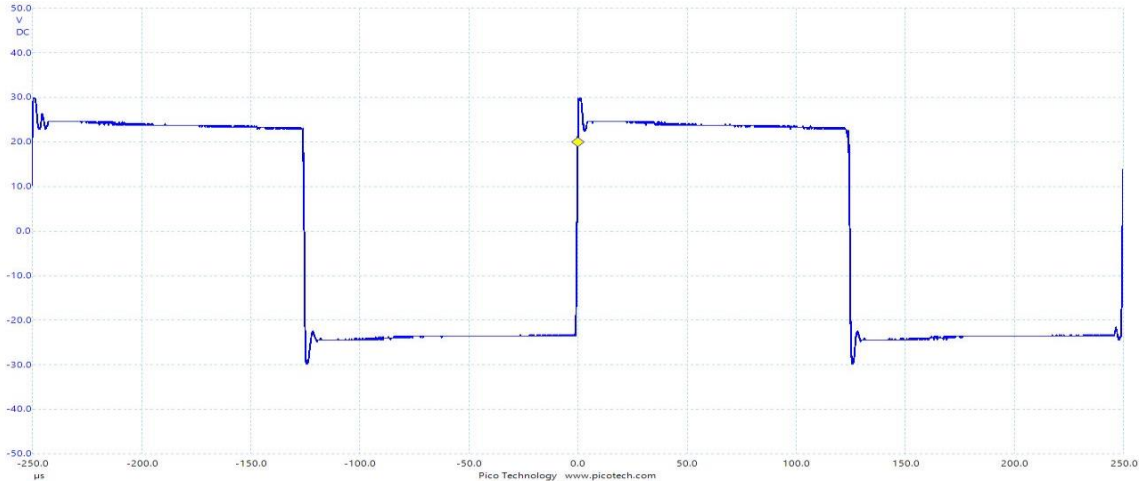
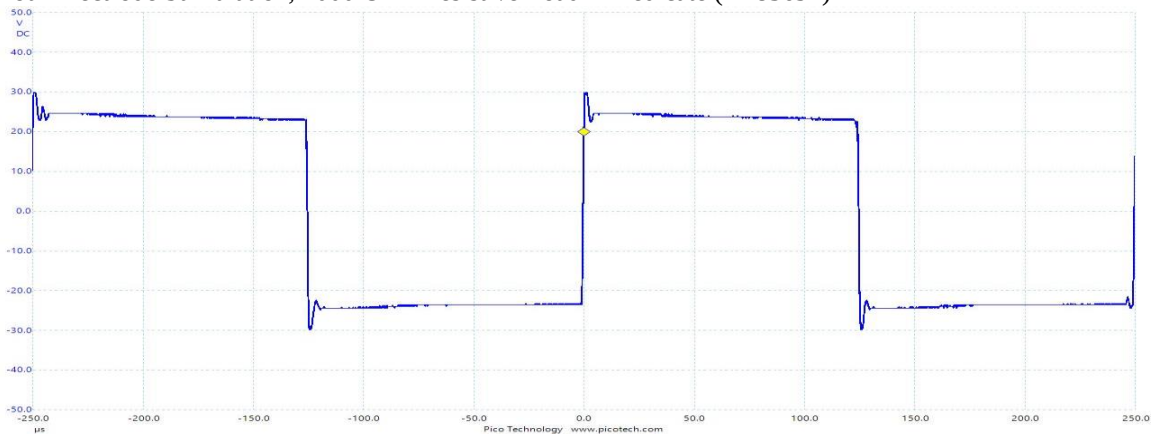


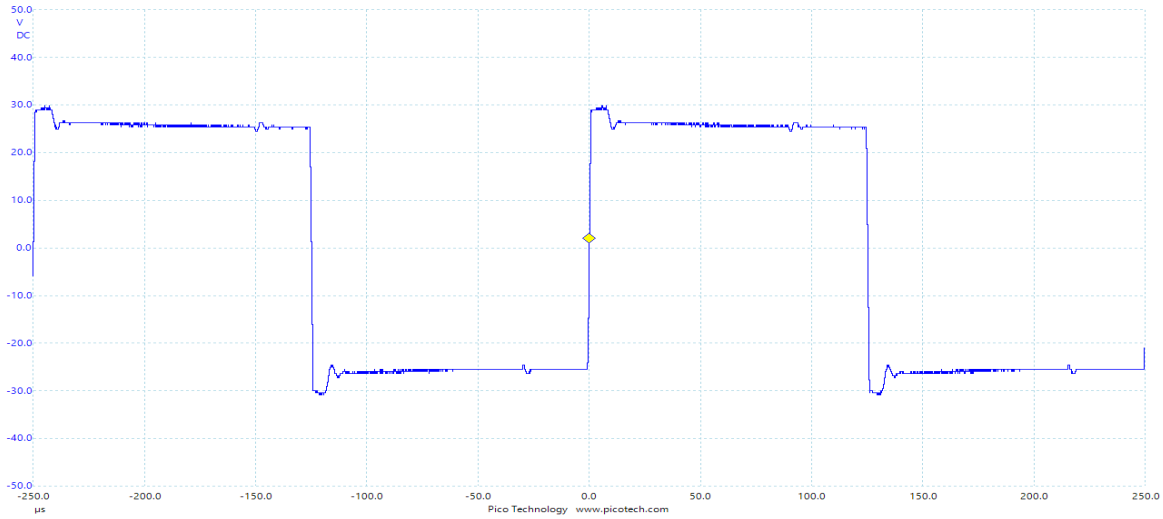
Four Electrode Stimulation, 2000 Ohm Resistive Load – Avid CT2



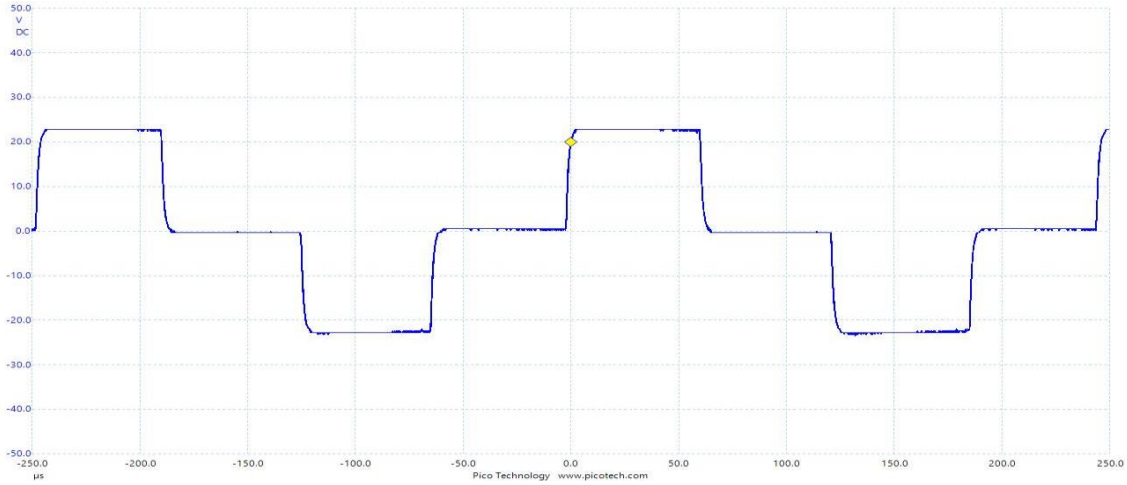
Four Electrode Stimulation, 2000 Ohm Resistive Load – Predicate (K183692)



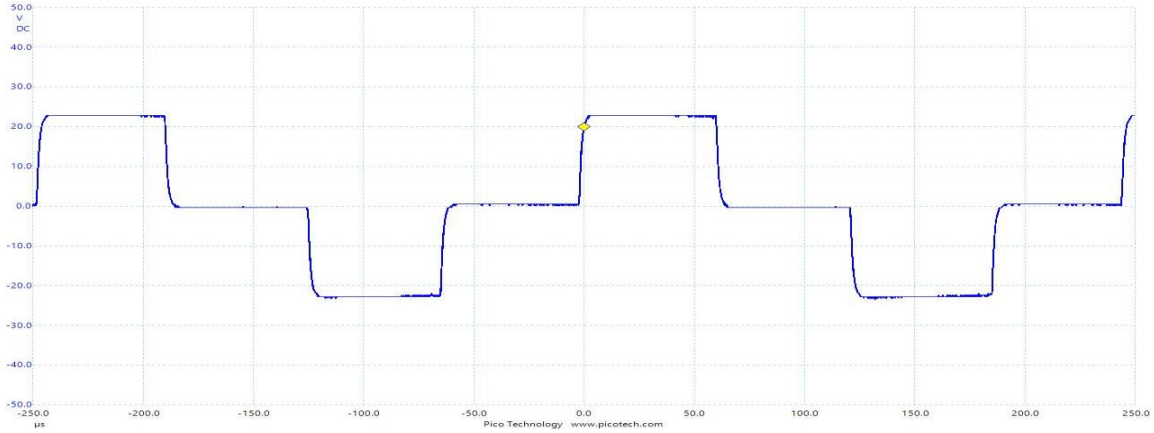
Four Electrode Stimulation, 2000 Ohm Resistive Load – Predicate (K982388)



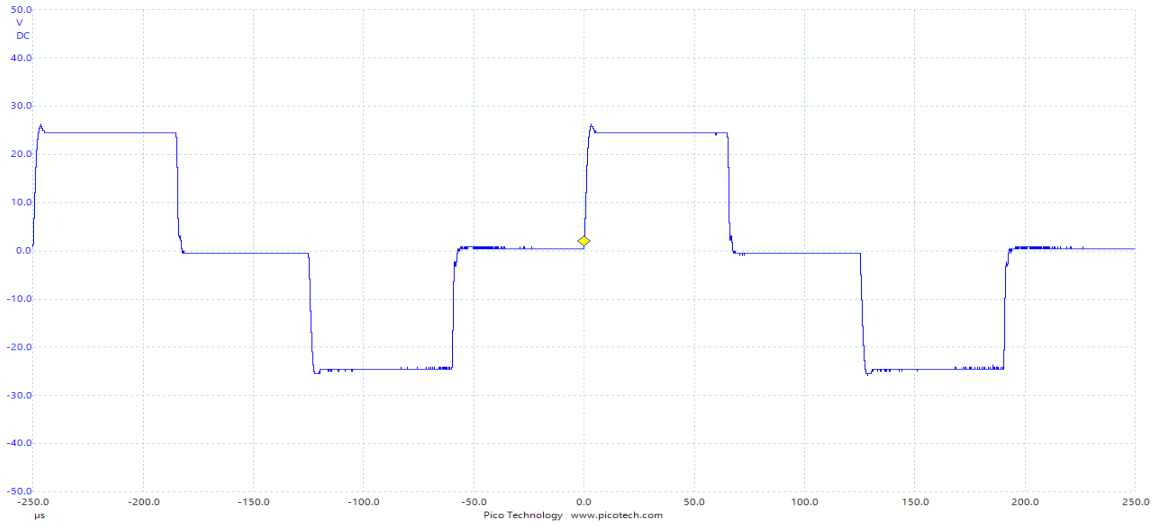
Two Electrode Stimulation, 500 Ohm Resistive Load – Avid CT2



Two Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K183692)



Two Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K982388)



Substantial Equivalence Summary

Based on the data contained in the previous two tables and comparison waveforms we conclude that the Avid CT2 is equivalent to its predicates.