June 12, 2019

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

Re: K183692
Trade/Device Name: Avid IF2 Interferential Stimulator, Model AV-IF19A
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: LIH
Dated: March 12, 2019
Received: March 14, 2019

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,

for Carlos Pena, PhD, MS
Director
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)*
K183692

Device Name
Avid IF2 Interferential Stimulator, Model AV-IF19A

Indications for Use *(Describe)*
The Avid IF2 Interferential Stimulator, Model AV-IF19A is indicated for use 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
-Maintaining and increasing range of motion
-Increases local blood circulation

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:	12/24/ 2018
Proprietary Name:	Avid IF2 Interferential Stimulator, Model AV-IF19A
Device Name and Classification:	Interferential Current Therapy Stimulator, Class II, 21 CFR 882.5890, Product Code LIH
Predicate Devices:	T.E.A.R. Tech3 by Vision Quest Industries, Inc. K030507 and K090532
Device Description:	The Avid IF2, Model AV-IF19A 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.
Statement of Intended Use:	The Avid IF2 Interferential Stimulator**,** Model AV-IF19A, is indicated for use 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 □ Maintaining and increasing range of motion □ Increases local blood circulation

Substantial Equivalence

The Avid IF2 is a generation design improvement to the company's previous device, the **T.E.A.R.** Tech3 IF/Muscle Stimulator. The company's previous models combined many stimulation modes in one device. The Avid IF2 only has the IF mode. **Therefore, as far as modes of stimulation is concerned the equivalency will be established by focusing on the IF mode.**

Indications for Use

The Avid IF2 has the same indications for use as the predicate devices when these are used in IF mode.

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 Stimulator is self-contained and includes two non-removable, rechargeable lithium ion batteries and an external power supply like the predicates.
- The Avid IF2 Stimulator also contains a single output jack for both output channels, and a user interface consisting of a touchscreen LCD for improved user experience. The device software contains self-tests for proper function and readiness. 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. The first 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 second predicate device from Vision Quest Industries, Inc. has four modes of stimulation: High Volt Pulsed Current (HVPC), Interferential (IF), Neuromuscular Electrical Stimulation (NMES) mode, and Pulsed Direct Current (PDC).

The next two tables compare the Avid IF 2 to its predicates.

Device Characteristics Comparison

510(k) Number Device Name **Manufacturer**	K030507 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	K090532 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	Unassigned Avid IF2 **Vision Quest Industries, Inc.**
Power Source	1 battery pack consisting of a Lithium-ion battery or 2 battery packs consisting of 3 'AA' alkaline cells each or external power supply	1 battery pack consisting of a Lithium-ion battery or 2 battery packs consisting of 3 'AA' alkaline cells each 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,HVPC,NMES, PDC)	1 (IF)
No. of Output Channels	IF Mode – 2 IF Mode – 1 NMES Mode- 2 HVPC Mode- 1	IF Mode – 2 IF Mode – 1 NMES Mode - 2 HVPC Mode - 1 PDC - 2	IF Mode – 2 IF Mode – 1
Synchronous or Alternating	IF – Synchronous NMES – Synchr. Or Alt. HVPC – Synchr. Or Alt.	IF – Synchronous NMES – Synchr. Or Alt. HVPC – Synchr. Or Alt. PDC – Synchronous	IF - Synchronous
Method of Channel Isolation	IF - Transformer coupled NMES - Transformer coupled HVPC – N/A	IF – Transformer coupled NMES – Transformer coupled HVPC – N/A PDC – Transformer coupled	IF – Transformer coupled
Reciprocal	IF - No NMES - Yes HVPC - Yes	IF – No NMES – Yes HVPC – Yes PDC – No	IF – No
Regulated Current or Regulated Voltage	IF – Regulated voltage NMES – Regulated current HVPC – Regulated voltage	IF – Regulated voltage NMES– Regulated current HVPC – Regulated voltage PDC – Regulated current	IF – 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	Yes	Yes	Yes
Automatic No-Load Trip	Yes (w/override option)	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

Device Characteristics Comparison

510(k) Number Device Name **Manufacturer**	K030507 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	K090532 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	Unassigned Avid IF2 **Vision Quest Industries, Inc.**
Voltage/Current Level	5.75V	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 NMES- Yes HVPC- No	IF – No NMES – Yes HVPC – No PDC – Yes	IF – No
Constant Voltage	IF- Yes NMES- No HVPC- Yes	IF – Yes NMES – No HVPC – Yes PDC – No	IF – Yes
Timer Range (minutes)			
Timer Settings	1 min to 24 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)	Yes	Yes	Yes
Weight (with batteries)	10.6 oz.	10.6 oz.	6.8 oz.
Dimensions (inches)	5.7 x 3.0 x 1.5	5.7 x 3.0 x 1.5	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
(Drawings are provided on following pages)

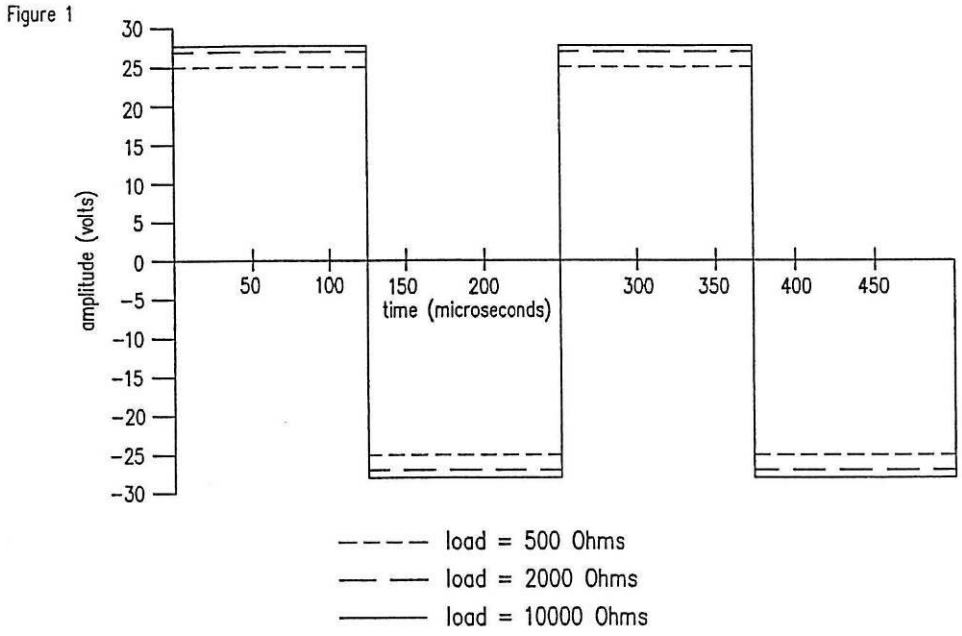
The waveform drawings are provided in accordance with the "Guidance Document for Powered Muscle Stimulator 510(k) s".

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

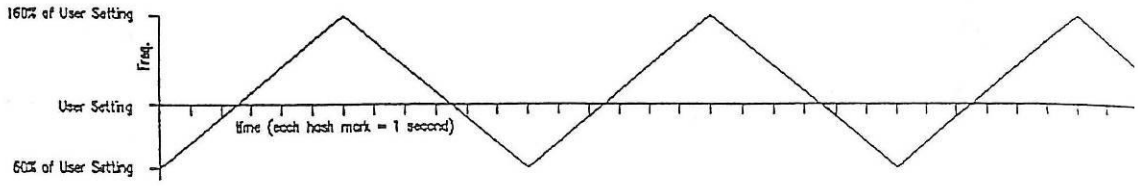
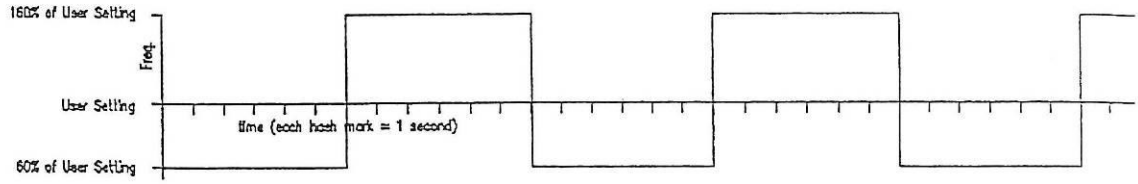


Figure 2



Waveform Description

The waveforms from the Avid IF2 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.

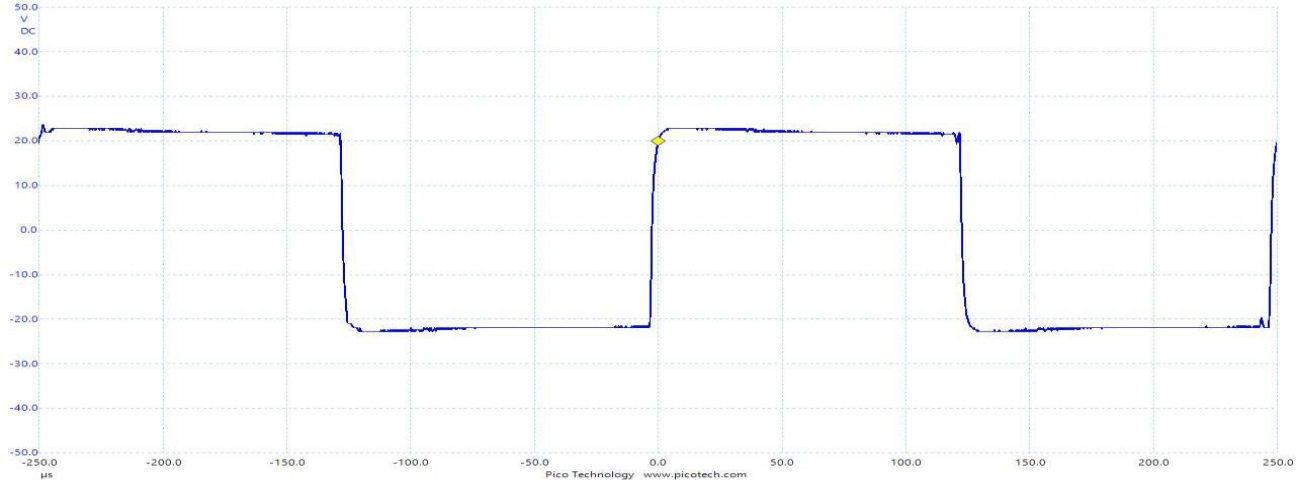
Output Specifications Comparison

510(k) Number Device Name **Manufacturer**	K030507 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	K090532 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	Unassigned Avid IF2 **Vision Quest Industries, Inc.**
Waveform	IF- Sym. Biphasic NMES– Sym/Asym. Biphasic HVPC- Twin peak pulsed monophasic	IF – Sym. Biphasic NMES – Sym/Asym. Biphasic HVPC – Twin peak pulsed monophasic PDC – Symmetrical biphasic and unbalanced triphasic	IF – Sym. Biphasic
Max. Output Current (500 Ohm Load)	IF Mode – 50mA ±10% NMES Mode- 100mA ±10% HVPC- .66A ±10%	IF Mode – 50mA+/- 10% NMES Mode – 100mA +/- 10% HVPC – .66A+/- 10% PDC – 100mA	IF Mode – 50mA+/- 10%
Max. Output Voltage (500 Ohm Load)	IF- 25V ± 10% NMES- 50V ±10% HVPC 330V ±10%	IF – 25V +/- 10% NMES – 50V +/- 10% HVPC – 330V +/- 10% PDC – 50V	IF – 25V +/- 10%
Shape	IF- Square or rectangular NMES- Rectangular wave HVPC- Dual exponential spike	IF – Square or rectangular NMES – Rectangular wave HVPC – Dual exponential spike PDC – Rectangular wave	IF – Square or rectangular
Symmetry	IF- Symmetrical NMES- Symmetrical or Asymmetrical HVPC - No	IF – Symmetrical NMES – Symmetrical or Asymmetrical HVPC – No PDC – Symmetrical and Asymmetrical	IF – Symmetrical
Net Phase Charge	IF - 0µC NMES – 0µC HVPC- 8.25µC	IF – 0µC NMES – 0µC HVPC – 8.25µC PDC – Symm. – 0µC Asymm. – 6µC	IF – 0µC
Peak Phase Current (500 Ohm)	IF – 50mA NMES – 100mA HVPC – 0.66A	IF – 50mA NMES – 100mA HVPC – 0.66A PDC – 100mA	IF – 50mA
Peak Phase Voltage (500 Ohm)	IF-25V NMES – 50V HVPC-330V	IF – 25V NMES – 50V HVPC – 330V PDC – 50V	IF – 25V
Phase Rise Time (500 Ohm, max.width)	IF - < 2µS NMES- <2µS HVPC- <1µS	IF - < 2µS NMES- <2µS HVPC- <1µS PDC – <2µS	IF - < 2µS
Phase Decay Time (500 Ohm, max. width)	IF- < 2µS NMES- <2µS HVPC- 27µS	IF- < 2µS NMES- <2µS HVPC- 27µS PDC – <2µS	IF- < 2µS
Phase Duration Range (at 50% max. width)	IF - 7µS – 125µS NMES - 30µS – 300µS HVPC- 5µS	IF - 7µS – 125µS NMES - 30µS – 300µS HVPC- 5µS PDC – 60µS	IF - 7µS – 125µS

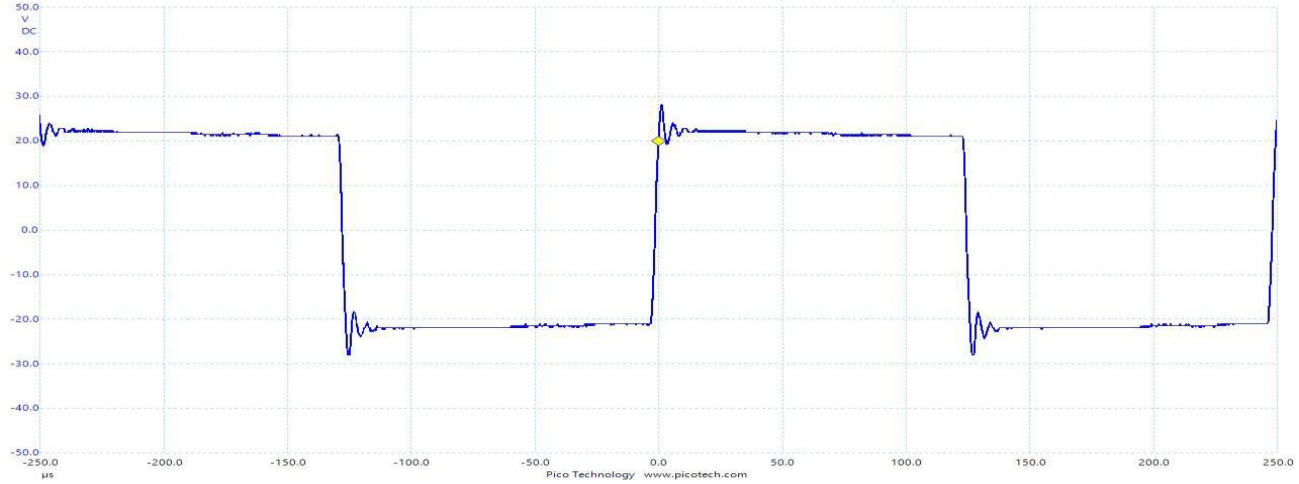
Output Specifications Comparison

510(k) Number Device Name **Manufacturer**	K030507 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	K090532 T.E.A.R. Tech3 **Vision Quest Industries, Inc.**	Unassigned Avid IF2 **Vision Quest Industries, Inc.**
Interphase Interval	IF – 0μS NMES – 0 - 250μS HVPC – 100 - 300μS	IF – 0μS NMES – 0 - 250μS HVPC – 100 - 300μS PDC – 900μS, 1800μS	IF – 0μS
Frequency Range	IF- 4000 Hz – 4240 Hz NMES - 1-200 Hz HVPC – 1-200 Hz	IF- 4000 Hz – 4240 Hz NMES- 1-200 Hz HVPC – 1-200 Hz PDC – Symm: 278Hz Asymm: 222Hz	IF- 4000 Hz – 4240 Hz
Interference Pattern	IF – Yes NMES - No HVPC – No	IF – Yes NMES - No HVPC – No PDC – No	IF – Yes
Beat Frequencies	IF- 1-240 Hz NMES – NA HVPC – NA	IF- 1-240 Hz NMES – NA HVPC – NA PDC – NA	IF- 1-240 Hz
Burst Mode	No	No	No
Current Density			
Peak (per sq. cm) (500 Ohm Load)	IF – 2.47mA NMES – 4.93mA HVPC – 65.1mA	IF – 2.47mA NMES – 4.93mA HVPC – 65.1mA PDC – 0.98mA	IF – 2.47mA
Ave. (per sq. cm) (500 Ohm Load)	IF – 1.235mA NMES – 0.295mA HVPC – 0.13mA	IF – 1.235mA NMES – 0.295mA HVPC – 0.13mA PDC – 0.059mA	IF – 1.235mA
Power Density			
Peak (per sq. cm) (500 Ohm Load)	IF – 61.7mW NMES – 247 mW HVPC – 10.7 W	IF – 61.7mW NMES – 247 mW HVPC – 10.7 W PDC – 49.4mW	IF – 61.7mW
Ave. (per sq. cm) (500 Ohm Load)	IF – 30.85mW NMES – 14.8 mW HVPC – 21.4 mW	IF – 30.85mW NMES – 14.8 mW HVPC – 21.4 mW PDC – 2.96mW	IF – 30.85mW
Max. Phase Charge			
500 Ohms	IF- 6.25μC NMES – 30 μC HVPC- 9.9 μC	IF- 6.25μC NMES – 30 μC HVPC- 9.9 μC PDC – 6μC	IF- 6.25μC
2K Ohms	IF- 1.56 μC NMES – 7.5 μC HVPC- 1.65 μC	IF- 1.56 μC NMES – 7.5 μC HVPC- 1.65 μC PDC – 1.5μC	IF- 1.56 μC
10K Ohms	IF- 0.33 μC NMES – 1.5 μC HVPC- 0.33 μC	IF- 0.33 μC NMES – 1.5 μC HVPC- 0.33 μC PDC – 0.3μC	IF- 0.33 μC

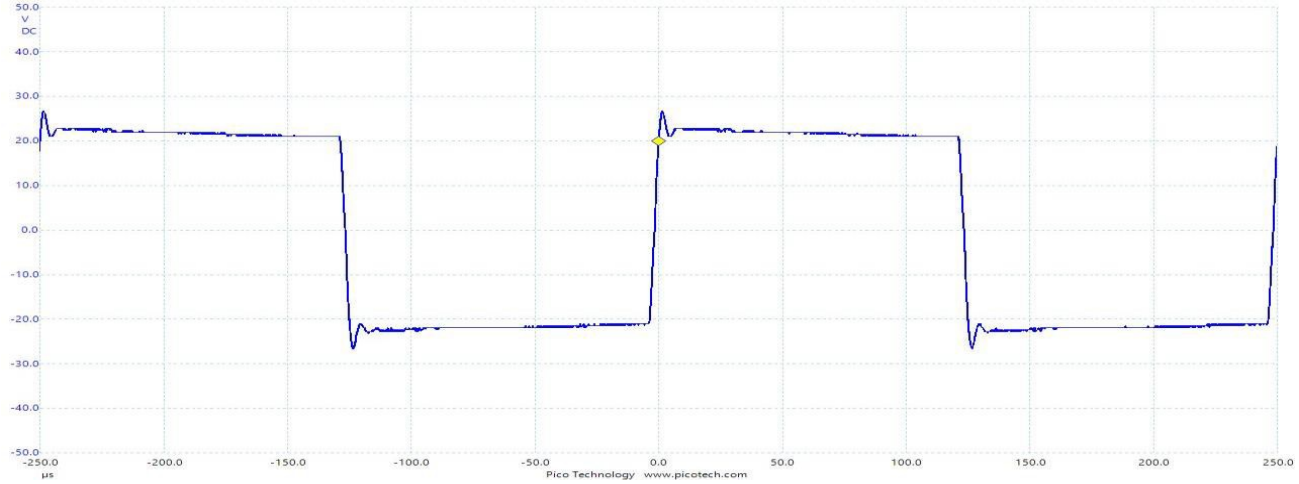
Four Electrode Stimulation, 500 Ohm Resistive Load – Avid IF2



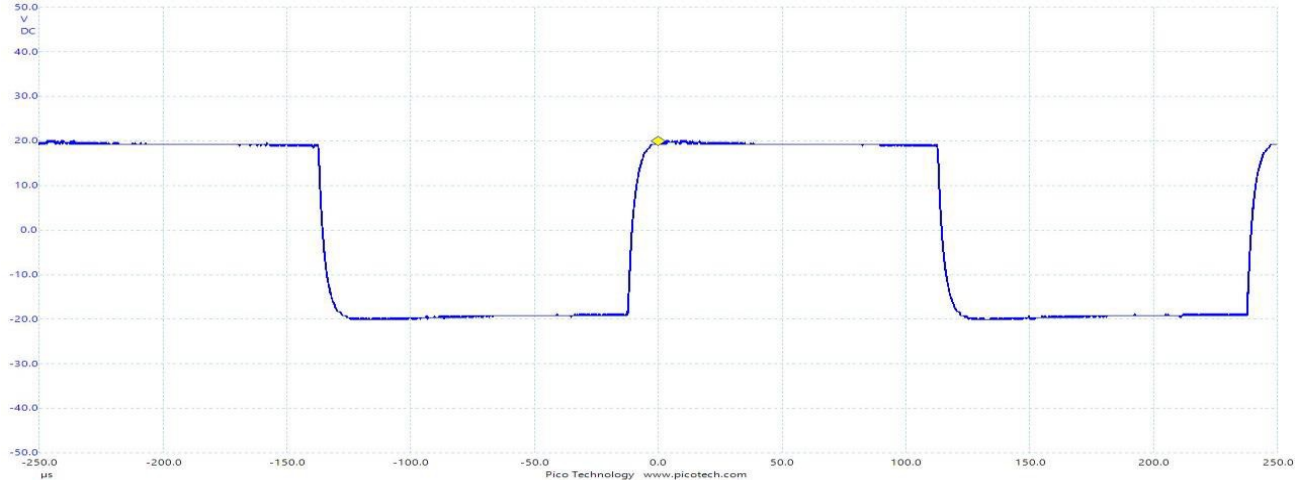
Four Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K090532)



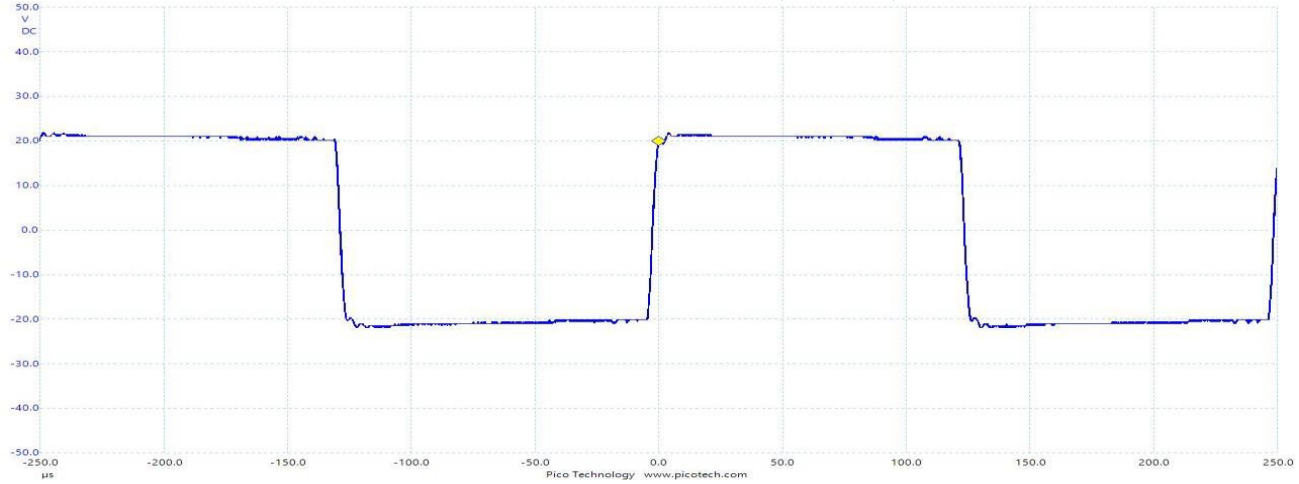
Four Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K030507)



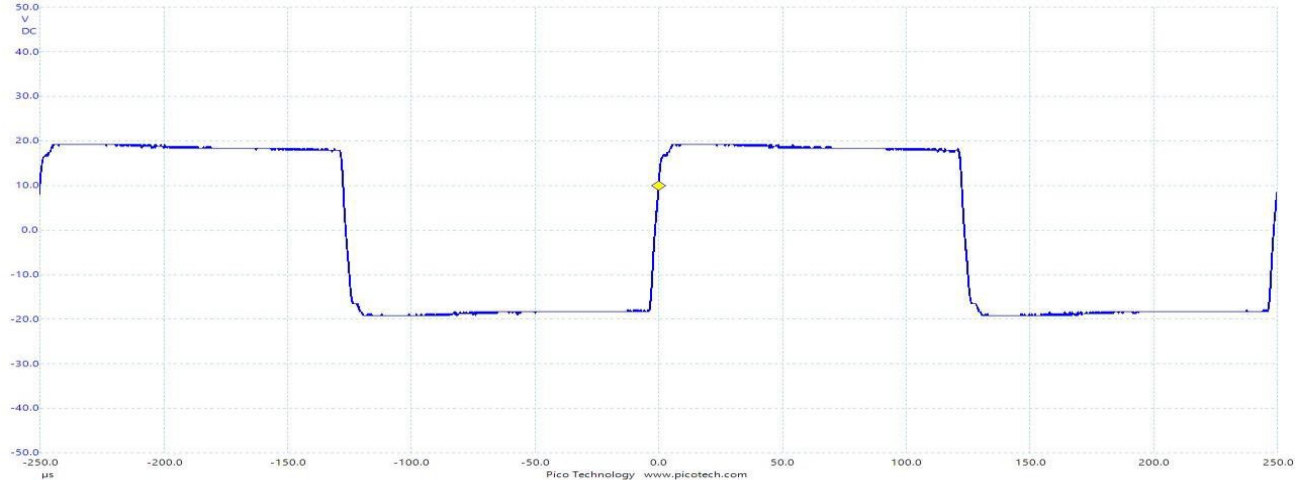
Four Electrode Stimulation, 200 Ohm Resistive Load – Avid IF2



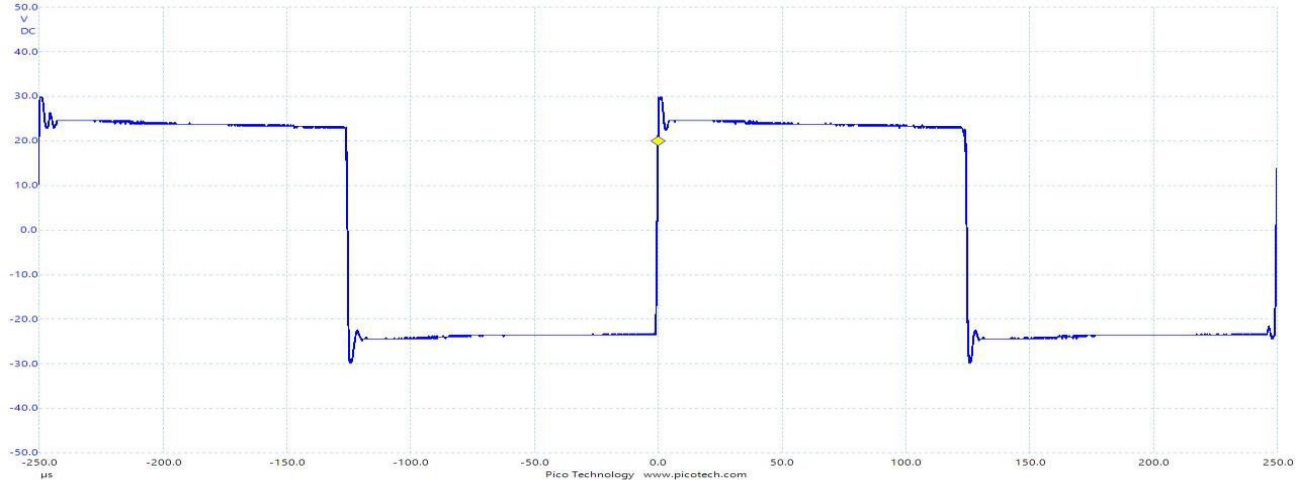
Four Electrode Stimulation, 200 Ohm Resistive Load – Predicate (K090532)



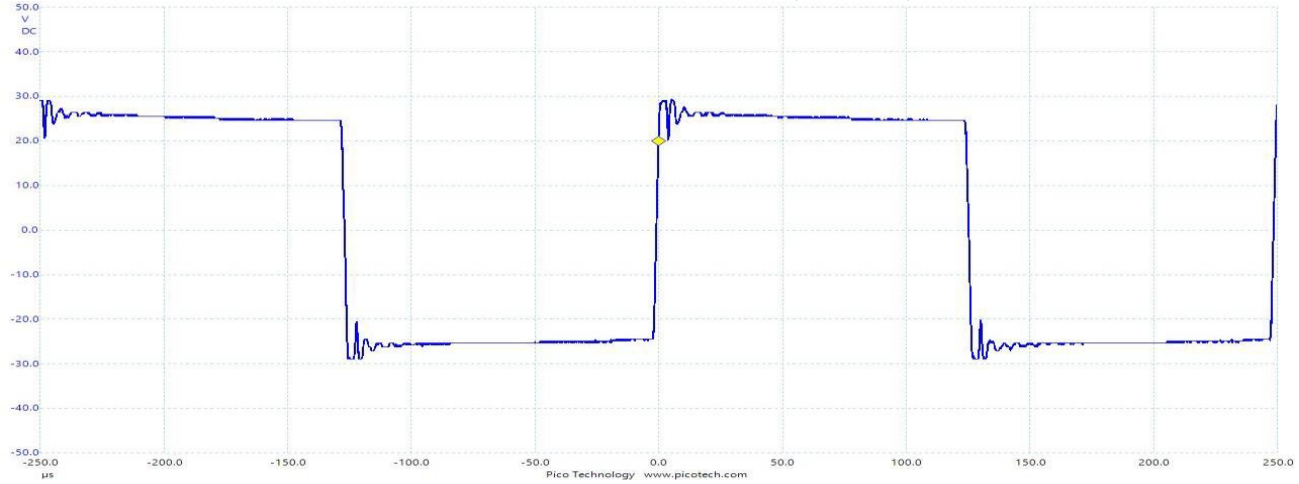
Four Electrode Stimulation, 200 Ohm Resistive Load – Predicate (K030507)



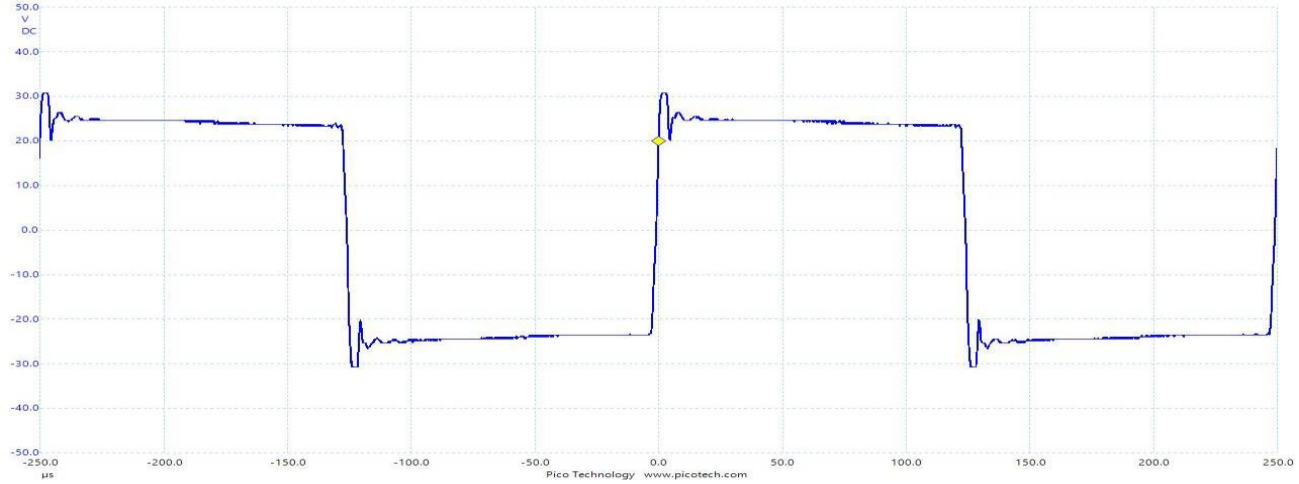
Four Electrode Stimulation, 2000 Ohm Resistive Load – Avid IF2



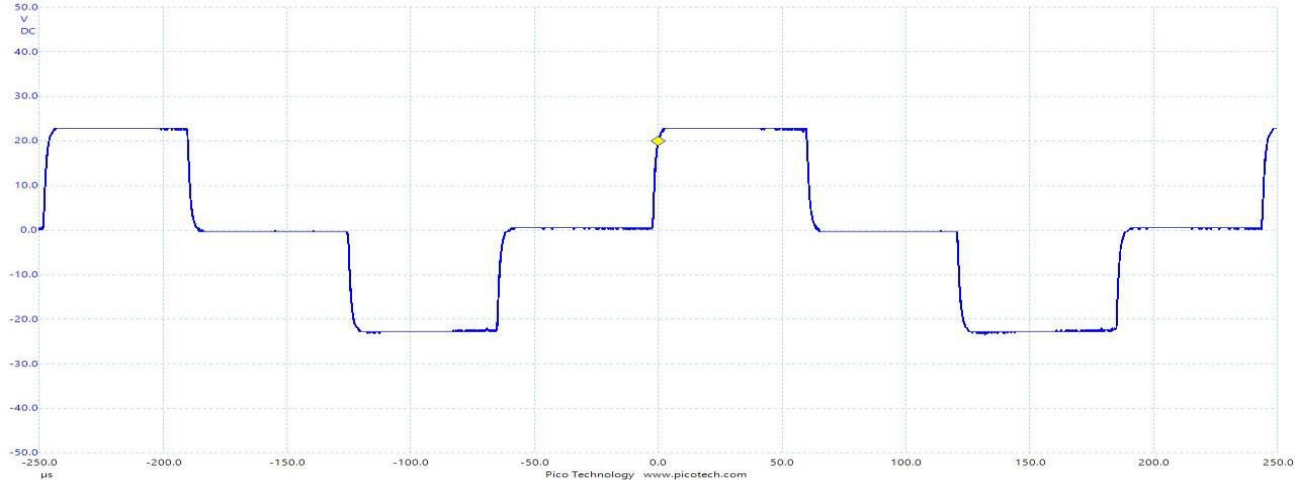
Four Electrode Stimulation, 2000 Ohm Resistive Load – Predicate (K090532)



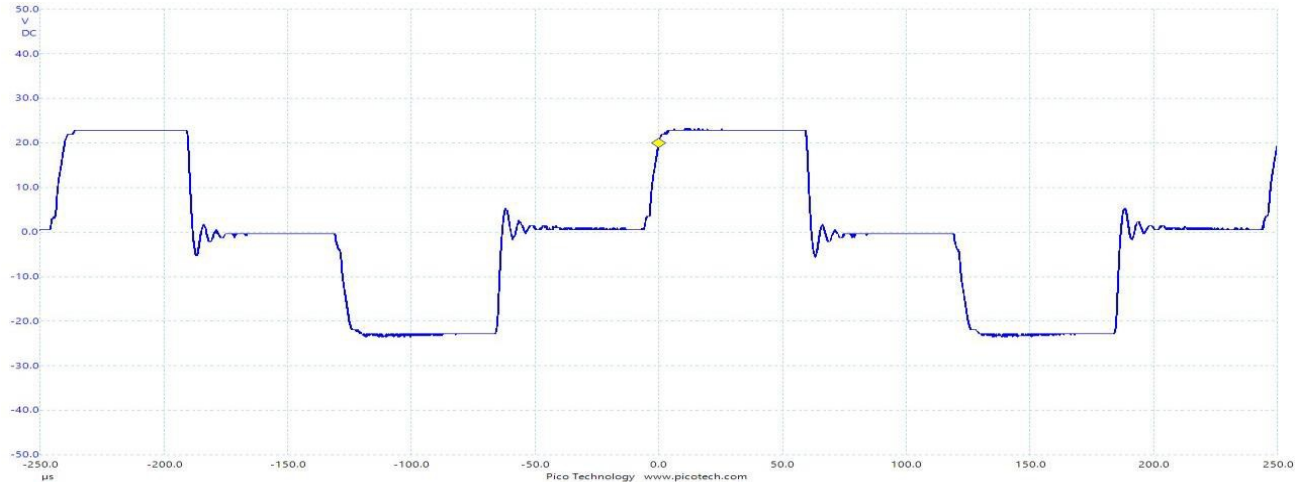
Four Electrode Stimulation, 2000 Ohm Resistive Load – Predicate (K030507)



Two Electrode Stimulation, 500 Ohm Resistive Load – Avid IF2



Two Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K090532)



Two Electrode Stimulation, 500 Ohm Resistive Load – Predicate (K030507)

Substantial Equivalence Summary

Based on the data contained in the previous two tables we conclude that the Avid IF2 is equivalent to its predicates. In addition, it provides cleaner wave forms and less voltage variation over load as shown in the scope traces of all three devices