



February 23, 2024

Hinge Health, Inc.
% Dawn Norman
Regulatory Consultant
EBG Advisors, Inc.
1227 25th Street, NW
Suite 700
Washington, District of Columbia 20037

Re: K233784

Trade/Device Name: ENSO (Model 2)
Regulation Number: 21 CFR 882.5890, 21 CFR 890.5850
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: November 10, 2023
Received: November 27, 2023

Dear Dawn Norman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert Kang -S

for Pamela Scott

Assistant Director

DHT5B: Division of Neuromodulation
and Rehabilitation Devices

OHT5: Office of Neurological
and Physical Medicine Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233784

Device Name

ENSO (Model 2)

Indications for Use (Describe)

A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities., and

A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles.

The ENSO Model 2 should be applied to normal, healthy, dry and clean skin of adult patients.

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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Traditional 510(k) Summary

Manufacturer: Hinge Health™ Incorporated
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San Francisco, CA 94105
USA
Phone (855) 902-2777

Contact Person: Dawn N. Norman, MS
Partner
MRC Global, LLC
Phone (618) 604-3064
Email: Dawn.Norman@askmrcglobal.com

Date Prepared: February 21, 2024

DEVICE INFORMATION

Trade/Proprietary Name: ENSO® Device System 510(k)

Common Name: Transcutaneous Nerve Stimulator
Classification Names: Transcutaneous Electrical Nerve Stimulator for Pain Relief, Powered Muscle Stimulator

21 CFR 882.5890 and 21 CFR 890.5850
Class II
Device Product Codes: NUH, NGX

PREDICATE DEVICE INFORMATION

Predicate Device: K160052 (CUR Model 1)

Trade/Proprietary Name: CUR Model 1

Common Name: Transcutaneous Nerve Stimulator
Classification Names: Stimulator, Nerve, Transcutaneous, Over-The-Counter

21 CFR 882.5890 and 21 CFR 890.5850
Class II
Device Product Codes: NUH, NGX

Product Description:

The Hinge Health ENSO® Device System consists of the main ENSO Device, a disposable Gel Pad, and a charging cable with AC adapter for recharging. The ENSO App is used to access and control the device.

The detailed device description and Engineering drawings for the ENSO® Device System can be found in Description Section of the eSTAR form.

The ENSO Device System that is the subject of this submission is a modification to the predicate Cur 1 Device System (K160052) that was cleared on May 20, 2016.

The subject of the present Traditional 510(k) submission is a modification of CUR Model 1. The device that is the subject of this 510(k) submission is identical to the predicate device (K160052) in terms of intended use, indications for use, charger function/materials, AC adaptor, gel pad tape, overall functionality, design, type of mating connections, biocompatibility and packaging. The subject device and the predicate share the same fundamental scientific technology and intended use.

Compared to the predicate device (K160052), the subject device uses several enhancements to improve device functionality and operation (see Performance Testing Section for details). The main changes are:

- Contraindications, remove implanted metal devices
- Extend gel pad expiration date period from 12mo to 18mo and then 18mo to 24mo
- Improve battery shelf life
- Minor software updates to add functionality and change system requirements.
- Add over-the-air (OTA) firmware update ability

There are no changes to the product's intended use, indications for use, functionality, biocompatibility, and packaging.

The ENSO Device System that is the subject of this submission meets the specifications for electrical output for TENS and EMS Modes, and IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 10993-1, ISO 10993-5 and -10.

Indications for Use (for this submission):

The Hinge Health ENSO Device System is intended to be used in the following: A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder,

waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. , and

A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles.

The ENSO Device should be applied to normal, healthy, dry and clean skin of adult patients.

With the exception of the addition of Hinge Health's "ENSO" brand name, there are no changes to the indications for use or intended use from the previously cleared CUR Model 1 predicate (K160052). Form FDA 3881, Indications for Use, can be found in the 510(k) submission. The addition of the "ENSO" brand name to the Indications for Use statement is not considered a change because the product line has been branded "ENSO" since it was launched in the USA in 2017.

Performance Testing

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the ENSO Device System was conducted in accordance with the various international standards listed below and in the Performance Testing - Bench Section of this 510(k) submission.

Performance testing of the subject device modification (ENSO 2) was conducted in accordance with the following standards and test methods as seen in Figure 5-1.

Figure 5-1 Test Method and Standards

Test Method	Standard(s)
Safety	IEC 60601-1
	IEC 60601-1-6
	IEC 60601-2-10
	IEC 60601-1-11
	IEC 60529
	IEC 62133-2
	IEC 62368
EMC	IEC 60601-1-2
	FCC §15.107 & ICES Issue 5, (Nov. 2014 Update), Conducted Emissions
	FCC §15.109 & CAN/CSA-CISPR 22-10 Table 6 and ICES-003 Issue 5 (Nov. 2014 Update), Radiated Emissions
	FCC § 1.1310, RF Exposure Evaluation
	RSS-102, Issue 5:2015+A1:2021, RF Exposure Evaluation
Software	IEC 62304

Test Method	Standard(s)
Usability	IEC 62366-1
Biocompatibility	ISO 10993-1
	ISO 10993-5
	ISO 10993-10
Packaging and Shelf-life	ASTM D6862 ASTM D3330/ ASTM D3331 ASTM F1980

Basis of Substantial Equivalence

The ENSO® Device System that is the subject of this submission has the following similarities to the predicate CUR Model 1 cleared under K160052:

- similar material
- same intended use
- same indications for use
- similar design
- similar sizes and dimensions
- same type of mating components
- same biocompatibility
- same packaging methods

Comparison Table – Indications for Use

Figure 5-2: Indications for Use Comparison Table

ENSO® Device System			
Attribute	Subject Device (ENSO 2, K233784)	Predicate (CUR Model 1, K160052)	Comments
Indications for Use	A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities., and A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles. The ENSO® Model 2 should be applied to normal, healthy, dry and clean skin of adult patients.	A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities., and A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles. The CUR Model 1 should be applied to normal, healthy, dry and clean skin of adult patients.	Identical, except for device name and model
Class	II	II	Identical
Product Code	NUH; NGX	NUH; NGX	Identical
Regulation	21 CFR 882.5890 and 21 CFR 890.5850	21 CFR 882.5890 and 21 CFR 890.5850	Identical

Comparison Table – Contraindications

Figure 5-3: Contraindications Comparison Table

ENSO® Device System			
Attribute	Subject Device (ENSO 2, K233784)	Predicate (CUR Model 1, K160052)	Comments
Contraindications	Contraindication: Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device. Such use could cause electric shock, burns, electrical interference, or death. Warning: Do not apply stimulation over or near metallic implants	Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.	Identical except “metallic” was removed and the warning was added

Comparison Table – Design Features

Figure 5-4: Design Feature Comparison Table

ENSO® Device System			
Attribute	Subject Device (ENSO 2, K233784)	Predicate (CUR Model 1, K160052)	Comments
Design Comparison	ENSO 2 is a wearable medical device that provides professional-grade transcutaneous electrical nerve stimulation (TENS) therapy along with an easy-to-use interface within a compact design. The device system consists of the main ENSO 2 Device, a disposable Gel Pad, and a charging cable with AC adapter for recharging the Device. ENSO 2 is controlled wirelessly using the Hinge Health app on a compatible Mobile Device.	CUR 1 is a wearable medical device that provides professional-grade transcutaneous electrical nerve stimulation (TENS) therapy along with an easy-to-use interface within a compact design. The device system consists of the main Cur 1 Device, a disposable Gel Pad, and a charging cable with AC adapter for recharging the Device. Cur 1 is controlled wirelessly using the Cur Mobile app on a compatible Mobile Device.	Identical
Sizes	Disposable gel pad- Large Disposable gel pad- Standard	Disposable gel pad	Identical

ENSO® Device System				
Attribute		Subject Device (ENSO 2, K233784)	Predicate (CUR Model 1, K160052)	Comments
Anatomical Sites		•shoulder •waist •back •neck •upper extremities (arm) •lower extremities (leg)	•shoulder •waist •back •neck •upper extremities (arm) •lower extremities (leg)	Identical
Biocompatibility/ Material		Tested per ISO 10993-1 ISO 10993-5 and -10	Tested per ISO 10993-1 ISO 10993-5 and -10	Equivalent biocompatibility results for gel pad and tape
Power Source(s)		Lithium-ion Polymer chemistry, and allow charging at 4.20V	3.7V Lithium-Polymer battery (rechargeable)	Equivalent or better battery life
Method of Line Current Isolation		Physically isolated; device cannot connect to electrodes and battery recharger concurrently	Physically isolated; device cannot connect to electrodes and battery recharger concurrently	Identical
Patient Leakage Current - Normal Condition (µA)		Battery powered ($< 10 \mu\text{A}$)	Battery powered ($< 10 \mu\text{A}$)	Identical
Patient Leakage Current - Single Fault Condition (µA)		Battery powered ($< 50 \mu\text{A}$)	Battery powered ($< 50 \mu\text{A}$)	Identical
Average DC current through electrodes when device is on but no pulses are being applied (µA)		$< 0.1\mu\text{A}$	$< 0.1\mu\text{A}$	Identical
Number of Output Modes		3 TENS, 1 EMS	3 TENS, 1 EMS	Identical
Number of Output Channels	1	1	1	Identical
	Method of Channel Isolation	N/A	N/A	Identical
Regulated Current or Regulated Voltage?		Yes	Yes	Identical
Software/Firmware/Microproces sor Control?		Yes	Yes	Identical
Automatic Overload Trip?		Yes	Yes	Identical

ENSO® Device System				
Attribute		Subject Device (ENSO 2, K233784)	Predicate (CUR Model 1, K160052)	Comments
Automatic No-Load Trip?		Yes	Yes	Identical
Automatic Shut Off?		Yes	Yes	Identical
User Override Control?		Yes	Yes	Identical
Indicator Display	On/Off Status?	Yes	Yes	Identical
	Low Battery?	Yes	Yes	Identical
	Voltage/Current Level?	Yes	Yes	Identical
Timer Range (minutes)		N/A	60 minutes	No time range
Compliance with Standards?		IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 10993-5 and -10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 10993-5 and -10	Identical
Compliance with 21 CFR 898?		N/A	N/A	Identical
Weight (g)		13.1g	11.5 g	1.6g heavier
Dimensions (mm) (W x H x D)		38 x 38 x 11	38 x 38 x 10	~1mm taller (D)
Housing Materials and Construction		Polycarbonate/PET Case	Polycarbonate plastic	Equivalent with more durability

Output Specifications Table for TENS Modes

Figure 5-5: Output Specification for TENS Mode Comparison Table

Output Specifications Table for TENS Modes							
Parameter	Subject Device (ENSO 2, K233784)			Predicate (CUR Model 1, K160052)			Comments
	Mode A (Default)	Mode B	Mode C	Mode A (Default)	Mode B	Mode C	
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic, Asymmetrical	Biphasic, Symmetrical	Biphasic, Symmetrical	Biphasic, Asymmetrical	Biphasic, Symmetrical	Biphasic, Symmetrical	Identical
Shape (e.g., rectangular, spike)	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Identical
Maximum Output Voltage (volts) (10+/- %)	42.6V @ 500Ω	43.2V @ 500Ω	42.9V @ 500Ω	42.6V @ 500Ω	43.2V @ 500Ω	42.9V @ 500Ω	Identical
	85.2V @ 2kΩ	85.4V @ 2kΩ	86.0V @ 2kΩ	85.2V @ 2kΩ	85.4V @ 2kΩ	86.0V @ 2kΩ	Identical
	87.0V @ 10kΩ	85.4V @ 10kΩ	87.8V @ 10kΩ	87.0V @ 10kΩ	85.4V @ 10kΩ	87.8V @ 10kΩ	Identical
Maximum Output Current (mA) (10+/- %)	85.1 mA @ 500Ω	86.3 mA @ 500Ω	85.6 mA @ 500Ω	85.1 mA @ 500Ω	86.3 mA @ 500Ω	85.6 mA @ 500Ω	Identical
	43.1 mA @ 2kΩ	43.2 mA @ 2kΩ	43.5 mA @ 2kΩ	43.1 mA @ 2kΩ	43.2 mA @ 2kΩ	43.5 mA @ 2kΩ	Identical
	8.8 mA @ 10kΩ	8.8 mA @ 10kΩ	8.8 mA @ 10kΩ	8.8 mA @ 10kΩ	8.8 mA @ 10kΩ	8.8 mA @ 10kΩ	Identical
Duration of primary (depolarizing) phase (usec)	25.85 usec	90.5 usec	51.0 usec	25.85 usec	90.5 usec	51.0 usec	Identical
Pulse Duration (both phases) (usec)	91.7 usec	221 usec	142 usec	91.7 usec	221 usec	142 usec	Identical
Frequency (Hz)	40-160 Hz	40-160 Hz	120-160 Hz	40-160 Hz	40-160 Hz	120-160 Hz	Identical
For multiphasic waveforms only:	N/A	N/A	N/A	N/A	N/A	N/A	Identical
Net Charge (microcoulombs (μC) per pulse) (If zero, state how this was achieved)	Nominally 0uC @ 500Ω, zero net current	Nominally 0uC @ 500Ω, zero net current	Nominally 0uC @ 500Ω, zero net current	Nominally 0uC @ 500Ω, zero net current	Nominally 0uC @ 500Ω, zero net current	Nominally 0uC @ 500Ω, zero net current	Identical
Maximum Phase Charge, (μC)	7.16 uC @ 500Ω	7.45 uC @ 500Ω	4.14 uC @ 500Ω	7.16 uC @ 500Ω	7.45 uC @ 500Ω	4.14 uC @ 500Ω	Identical
Maximum Current Density, (mA/cm2, r.m.s.)	0.009 mA/cm2 @500Ω	0.004 mA/cm2 @500Ω	0.006 mA/cm2 @500Ω	0.009 mA/cm2 @500Ω	0.004 mA/cm2 @500Ω	0.006 mA/cm2 @500Ω	Identical
Maximum Average Current (average absolute value), mA	0.94 mA @500Ω	1.85 mA @500Ω	1.28 mA @500Ω	0.94 mA @500Ω	1.85 mA @500Ω	1.28 mA @500Ω	Identical

Output Specifications Table for TENS Modes							
Parameter	Subject Device (ENSO 2, K233784)			Predicate (CUR Model 1, K160052)			Comments
	Mode A (Default)	Mode B	Mode C	Mode A (Default)	Mode B	Mode C	
Maximum Average Power Density, (W/cm ²), (using smallest conductive surface area)	1.50 mW/cm ² @500Ω	3.05 mW/cm ² @500Ω	2.09 mW/cm ² @500Ω	1.50 mW/cm ² @500Ω	3.05 mW/cm ² @500Ω	2.09 mW/cm ² @500Ω	Identical
Burst Mode (i.e., pulse trains):	N/A	N/A	N/A	N/A	N/A	N/A	Identical

Output Specifications Table for EMS Modes

Figure 5-6: Output Specifications for EMS Mode Comparison Table

Output Specifications Table for EMS Modes			
Parameter	Subject Device (ENSO 2, K233784)	Predicate (CUR Model 1, K160052)	Comments
Mode or Program Name	Measured (or Nominal as noted)	Measured (or Nominal as noted)	Identical
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic, Symmetrical	Biphasic, Symmetrical	Identical
Shape (e.g., rectangular, spike)	Rectangular	Rectangular	Identical
Maximum Output Voltage (volts) (10+/- %)	38.4V @ 500Ω	38.4V @ 500Ω	Identical
	85.0V @ 2kΩ	85.0V @ 2kΩ	Identical
	85.0V @ 10kΩ	85.0V @ 10kΩ	Identical
Maximum Output Current (mA) (10+/- %)	76.7 mA @ 500Ω	76.7 mA @ 500Ω	Identical
	43.0 mA @ 2kΩ	43.0 mA @ 2kΩ	Identical

Output Specifications Table for EMS Modes				
Parameter		Subject Device (ENSO 2, K233784)	Predicate (CUR Model 1, K160052)	Comments
		8.1 mA @ 10k Ω	8.1 mA @ 10k Ω	Identical
Duration of primary (depolarizing) phase (usec)		221.5 usec	221.5 usec	Identical
Pulse Duration (both phases) (usec)		483.8 usec	483.8 usec	Identical
Frequency (Hz)		2-15 Hz	2-15 Hz	Identical
For multiphasic waveforms only:	N/A	N/A	N/A	Identical
Net Charge (microcoulombs (μ C) per pulse) (If zero, state how this was achieved)		Nominally 0 μ C @ 500 Ω , zero net current	Nominally 0 μ C @ 500 Ω , zero net current	Identical
Maximum Phase Charge, (μ C)		16.21 μ C @ 500 Ω	16.21 μ C @ 500 Ω	Identical
Maximum Current Density, (mA/cm ² , r.m.s.)		0.006 mA/cm ² @500 Ω	0.006 mA/cm ² @500 Ω	Identical
Maximum Average Current (average absolute value), mA		0.22 mA @500 Ω	0.22 mA @500 Ω	Identical
Maximum Average Power Density, (W/cm ²), (using smallest conductive surface area)		0.315 mW/cm ² @500 Ω	0.315 mW/cm ² @500 Ω	Identical
Burst Mode (i.e., pulse trains):	N/A	N/A	N/A	Identical

Sterility and Shelf Life Specifications Table

Figure 5-7: Sterility and Shelf Life Comparison Table

Attribute	Subject Device	Predicate	Comments
Device Usage	Reusable	Reusable	Identical
Sterility	Provided non-sterile	Provided non-sterile	Identical
Expiration dating/ Shelf life	2-year gel pad expiration date	1 year gel pad expiration date	Gel pad expiry extended based on validation testing. See Sterilization and Shelf-life Section.

Clinical Testing

Hinge Health determined that bench and non-clinical testing were sufficient to demonstrate that the ENSO Device System is as safe and effective as the predicate device.

Conclusion:

The data and information provided in this submission support the conclusion that the ENSO Device System that is the subject of this 510(k) submission is substantially equivalent to its predicate device (K160052), and does not significantly affect the safety or effectiveness of the device. This modification is being proposed to improve device functionality, operation and is not at result of any clinical or performance factors.