April 10, 2020

Esthetic Education LLC
% Marc Sanchez
Attorney & Regulatory Consultant
Contract In-House Counsel and Consultants, LLC
(d/b/a FDA Atty)
53516 Bickett
Chapel Hill, North Carolina 27517

Re: K200044
Trade/Device Name: SkinStylus SteriLock MicroSystem
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: January 6, 2020
Received: January 8, 2020

Dear Marc Sanchez:

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K200044

Device Name
SkinStylus SteriLock® MicroSystem

Indications for Use *(Describe)*
The SkinStylus SteriLock® MicroSystem is intended to be used as a treatment to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen in adults aged 22 years or older.

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

The following information is provided as required by 21 CFR 807.92 for the SkinStylus SteriLock® MicroSystem 510(k) premarket notification.

Sponsor: Esthetic Education LLC
7950 E. Acoma Drive Suite 100
Scottsdale, AZ 85260

Establishment Registration: 3011338460

Manufacturer: GUANGZHOU CARAIN BEAUTY EQUIPMENT
103 & 601, No. 3 of Xin Liu Mu Road,
Zhong Cun Street
Guangzhou Guangdong, CHINA 511495
Establishment Registration: 3011568699

Contact: Marc C. Sanchez, Esq.
Contract In-House Counsel and Consultants, LLC (d/b/a FDA Atty)
53516 Bickett Chapel Hill NC 27517
Ph: 202.765.4491
E-mail: msanchez@fdaatty.com

Date Prepared: April 7, 2020

Proprietary Name: SkinStylus SteriLock® MicroSystem

Common Name: Powered Microneedle Device

Regulation Number: 21 CFR 878.4430

Regulatory Class: Class II

Product Code: QAI

Predicate Device(s): SkinPen Precision System (DEN160029)

Device Description:

The SkinStylus SteriLock® MicroSystem is a handheld device that creates microinjuries into the skin, by virtue of a 1A DC motor that rapidly reciprocates an array of 32 gauge microneedles that are no longer than 2.5mm. The device consists of a power source, a motor body with depth adjustment, a removable nosecone interface, and a disposable, single use cartridge containing an array of microneedles.

The power source consists of two separate systems. One option is a rechargeable lithium-ion battery that delivers no more than 5 volts DC and 1 amp of current to power the motor. The other option consists of an AC wall adaptor that converts 110v AC into 5v DC. A power cord connects the wall adaptor to the device via a USB connector and a standard 1/8" headphone plug on the device side.

The motor body is comprised of anodized aluminum with a dial mechanism that controls the depth of penetration of the microneedles from 0.0 mm to a maximum of 2.5mm.

The removable nosecone provides the SkinStylus® with an interface between the motor and the cartridge to prevent any fluid from entering the motor body. The removable nosecone is autoclave sterilized or intermediate-level disinfected after every use.

The SkinStylus® disposable cartridge is designed in three configurations, a 12-needle array with all needles at 2.5mm, a 36-needle array with all needles at 2.5mm and a 36-needle array with 18 needles at 1.0mm and 18 needles at 2.5mm. The needle array is housed in a specially designed and patented cartridge housing that prevents liquids from entering the motor body via the inside lumen of the cartridge.

The SkinStylus SteriLock® microneedles are composed of 304 18/8 surgical steel.

Each lot of cartridges are individually packaged and then gamma ray sterilized.

Table 2 Technological Characteristics

Device Name/Model	SkinStylus SteriLock® MicroSystem	SkinPen Precision System
510(k) Number	K200044	DEN160029
Indication for Use	Intended to be used as a treatment to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen in adults aged 22 years or older.	Intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older
Mode of Action	Microneedling (using one or more needles to mechanically puncture and injure skin tissue for aesthetic use)	Same
Power Source 1	5 Volt DC/1 amp rechargeable lithium-ion battery	5 Volt DC/1 amp rechargeable lithium-ion battery
Power Source 2	110 AC converted to 5 Volt DC/1 amp	AC Adapter 5VC +/-, 1A minimum
Range of Needle Length	0.25mm-2.5mm	0.25mm-2.5mm
Maximum Penetration	2.5mm	2.5mm

Needle Geometry	Array 1) 36 solid needles all at 2.5mm. Array 2) 18 solid needles at 2.5mm and 18 pins at 1.0mm alternating rows. Array 3) 12 solid needles all at 2.5mm All needles 32 SWG Radius 0.008mm (Max)	14 solid needles (32 BWG; Radius 0.005mm (Max))
Speed	6200- 8840 RPM	6300RPM-7700 RPM
Cross Contamination Safety Feature	Cartridge design and intermediate disinfected handpiece and nosecone with optional reprocessed (autoclave sterilized) nosecone;	Cartridge design and BioSheath
Sterility and Cleaning	Disposable cartridge Gamma Ray Sterilized prior to packaging	Disposable cartridge Ethylene Oxide Sterilized prior to packaging
Clinical Trial to Support Intended Use and Safety	YES	YES

Intended Use:

The SkinStylus SteriLock® MicroSystem is intended to be used as a treatment to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen in adults aged 22 years or older.

Summary of Clinical Test Reports

A clinical study was conducted to support the safety and effectiveness of the SkinStylus SteriLock® MicroSystem for the treatment of scars on the abdomen.
The study was conducted at a single center and included treatments on day 1, day 15, and day 31, with follow-up visits at 90 days from day 31 and 6 months after the final (day 31) treatment. Treatments were conducted by licensed and trained aestheticians (skin care specialists) who were supervised by a licensed dermatologist. The scar was photographed and then was divided into a treatment half and a control half. Both sides were cleaned and numbed prior to treatment. A thin layer of lubricant was applied to both sides prior to treatment to protect against abrasion and friction during the procedure. The aestheticians were instructed to start at a depth setting of 1.0 mm and increase the depth to 2.5mm on all patients until localized petechia and mild, localized capillary bleeding was observed on the treatment side of the scar structure. All three cartridge types were used on every patient and all patients received some portion of each treatment at a depth of 2.5mm. Following treatment, the area was cleaned with sterile saline and a sterile gauze dressing was applied.
A total of 34 subjects completed the study. 30 of those subjects had a scar located on the abdomen. Subjects enrolled in the study included men (5.8%) and women (94.2%) over age 22. The study included 12/34 subjects with Fitzpatrick Skin Type (FST) IV - VI.

Table 1: Summary of Demographic Information

Total # of subjects applies	38		Sex	#	%
Total # of subjects approved after screening	36		Male	2	5.88%
Total # of subjects completing trial	34		Female	34	94.20%
Total # of subjects completing trial with scar on abdomen	30		Ethnicity		
Mean Age (years)	47.50		Hispanic or Latino	9	26.47%
Mean (standard deviation)	1.52		Non-Hispanic or Latino	27	79.41%
Minimum	26		Race		
Maximum	60		American Indian or Alaskan Native	1	2.94%
			Asian	2	5.88%
			Black or African American	2	5.88%
			White	31	91.18%

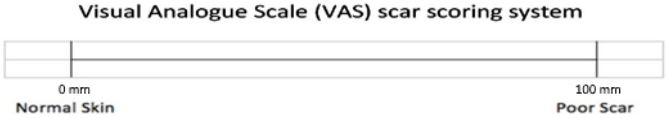
			Fitzpatrick Skin Type		
			I	1	2.94%
			II	13	38.24%
			III	12	35.29%
			IV	7	20.59%
			V	3	8.82%
			VI	2	5.88%

At each clinical visit, digital images were taken of each subject's scars, before and after treatment. After the first treatment, on each subsequent treatment, objective and subjective data were obtained from patients regarding the occurrence of any adverse event or other sequel. On day 1, day 15, and day 31 imaging was performed before and after treatment. 90 days after the last treatment (day 31), grading images were obtained. These images were graded by the following blinded graders: a Board Certified Dermatologist and two Board Certified Plastic Surgeons after completion of the study using the following assessment tools [Table 2]. Details of each of these assessment tools are provided below in Tables 3 and 4. The results of the study are provided in Tables 5 and 6.

Table 2: Study Endpoints

Primary Effectiveness Endpoint	The primary endpoint was established as a 10 mm (10mm is the Minimal Clinical Important Difference (MCID) for the validated Visual Analogue Scale) improvement in the treatment side of the scar using the 100 mm validated VAS scale observed by at least 2 out of 3 blinded graders compared to the non-treatment side 90 days after last of 3 treatments. The treatment site photos were also correlated to the graded non-treatment side control photos.
Secondary Effectiveness Endpoint	Self-assessed Scar Improvement Scale completed by subjects at 90 days after last of 3 treatments on the same side.
	Subject Global Aesthetic Improvement Scale completed by subjects at 90 days after last of 3 treatments on the same side.
Safety Endpoint	Adverse event monitoring at each visit; treatment 2, treatment 3, 90 days after treatment 3, and 6 months after treatment 3.

The photo grading included the following effectiveness assessments using a 100 mm VAS scale:



Each subject had a scar on the abdomen that had been photographed and divided into a treatment segment and an untreated/control segment, roughly equal in length to each other. The same half of the scar was treated with microneedling on three separate treatment appointments at least 14 days apart. At each of the three treatment appointments, a different cartridge array type was used, but the order was randomized and each subject had to receive one treatment from each of the three cartridges.

At 90 days after the last treatment, both sides of the scar (treated side and untreated/control side) were photographed. The photographs were not retouched and were arranged in pairs on Powerpoint®slides. Each slide contains two images from the same subject randomly arranged so that the grader did not know whether the slide with the two treated side images was presented before or after the slide with the two non-treated side images. Additionally, while both images on the slide came from the same subject, the grader did not know which image represented the before or after condition.

On each set of slides there was a horizontal, 100 mm line located under each image. This line represents a VAS scale where the far left end is marked as "0.0 mm" and represents "Normal Skin" and the far right end is marked at "100 mm" and represents a "Poor Scar".

Each of the three graders, comprised of a Board Certified Dermatologist and two Board Certified Plastic Surgeons were asked to view each slide and grade each image by using a mouse to grab the vertical line and place it on the horizontal VAS scale line in a position that indicated his/her professional opinion of the relative condition of the scar observed in the image.

In addition to the clinician graded effectiveness measures, the following patient-reported measures were recorded throughout the study:

Table 3: Self-assessed Scar Improvement Scale

Rating	Description
-1	Exacerbation of scars
0	No change in appearance of scars
1	1% - 25% improvement in appearance of scars
2	25% - 50% improvement in appearance of scars
3	50% - 75% improvement in appearance of scars
4	75% - 99% improvement in appearance of scars

Table 4: Subject Global Aesthetic Improvement Scale

Rating	Description
1	Very Much Improved: Optimal cosmetic result.
2	Much Improved: Marked improvement in appearance from the initial condition, but not completely optimal.
3	Improved: Obvious improvement in appearance from initial condition.
4	No Change: The appearance is essentially the same as the original condition.
5	Worse: The appearance is worse than the original condition.

Primary Endpoint Results

From the evaluation of the patient data collected during the study, the mean difference in VAS scores on the treatment side was found to be greater than the mean difference in VAS scores on the control side. This result indicates that the SkinStylus SteriLock®MicroSystem was found to improve the appearance of abdominal scars, measured using the VAS scar scoring system. The Minimal Clinically Important Difference (MCID) has been established as an improvement of at least 10 mm out of 100 mm (the entire VAS length).

The primary endpoint was established as a 10 mm (10 mm is the MCID for the VAS) improvement in the treatment side of the scar using the 100 mm validated VAS scale observed by at least 2 out of 3 blinded graders compared to the non-treatment side. Out of the 30 abdomen subjects that completed the trial and had their abdomen treated, 22 subjects had at least a 10 mm improvement, compared to the non-treated side, according to at least 2 of the 3 blinded evaluators. This results in a responder rate of 73% with 95% CI from 58% to 89%.

The visual improvements seen in the photo grading results after only 90 days after the last treatment, were considered to be clinically meaningful as the non-treatment side was also graded and compared against the treatment side results.

Table 5: Responder rates by Fitzpatrick Skin Type according to VAS improvement of 10mm Minimum Clinically Important Difference (MCID) by at least 2 out of 3 graders.

Fitzpatrick Skin Type	# of subjects in Fitzpatrick Skin Type	# of responders	Percent responding	95% CI for responder rate (%)
Skin Type I to III	18	12	67%	(45, 88)
Skin Type IV to VI	12	10	83%	(62,100)

Table 6: Responder rates by age group according to VAS improvement of 10mm Minimal Clinically Important Difference (MCID) by at least 2 out of 3 graders.

Age Group	# of subjects in age group	# of responders	Percent responding	95% CI for responder rate (%)
21 to 40 years old	9	8	89%	(68, 100)
41 to 50 years old	10	7	70%	(42, 99)
51 to 60 years old	10	7	64%	(35, 92)

Table 7: Responder rates by age of scar group according to VAS improvement of 10mm Minimal Clinically Important Difference (MCID) by at least 2 out of 3 graders.

Age of scar	# of subjects with scar in age range	# of responders	Percent responding	95% CI for responder rate (%)
0 to 105 months old	22	17	77%	(60, 95)
106 to 180 months old	5	3	60%	(17,100)
181 to 240 months old	3	2	67%	(13,100)

Secondary Endpoint Results

The patient survey results for the Self-Assessed Scar Improvement Scale (SASIS) survey and for the Subject Global Aesthetic Improvement Scale (SGAIS) survey are reported in Tables 8 and 9, respectively.

In the SASIS survey, scores of 1, 2, 3, and 4 indicate perceived improvement in the scar appearance (improvement between 1% and 100%), while a score of -1 means the scar appears worse and a score of 0 means the scar appears unchanged. In the SGAIS survey, scores of 1, 2, and 3 indicate perceived improvement in the scar appearance (very much improved, much improved, and improved), while a score of 4 means the scar is unchanged and a score of 5 means the scar appears worse. Both surveys were evaluated as a measure of consistency in the patient results.

Out of the 30 subjects that completed the trial and had their abdomen treated, 28 had SASIS scores of 1 or greater indicating that they were satisfied with the treatment (93% with 95% CI from 84% to 100%.)

Out of the 30 subjects that completed the trial and had their abdomen treated, 19 had SASIS scores of 3 or greater indicating the they had seen a scar improvement higher than 50% (63% with 95% CI from 46% to 81%.)

Out of the 30 subjects that completed the trial and had their abdomen treated, 27 had SGAIS of 3 or lower indicated that they were satisfied with the treatment (90% with 95% CI from 79% to 100%.

Both surveys corroborated the results that patients were satisfied and saw improvement in the scar appearance after the three SkinStylus SteriLock®MicroSystem treatments.

Table 8. Self-assessed Scar Improvement Scale Results

	Rating					
	-1 Exacerbation of scars	0 No change in appearance of scars	1 1% - 25% improvement in appearance of scars	2 26% - 50% improvement in appearance of scars	3 51% - 75% improvement in appearance of scars	4 76% - 100% improvement in appearance of scars
Number of subjects	0	2	5	4	13	6
Percentage of subjects (%)	0	6	17	13	43	20

Table 9. Subject Global Aesthetic Improvement Scale Results

	Rating				
	1 Very Much Improved: Optimal cosmetic result.	2 Much Improved: Marked improvement in appearance from the initial condition, but not completely optimal.	3 Improved: Obvious improvement in appearance from initial condition.	4 No Change: The appearance is essentially the same as the original condition.	5 Worse: The appearance is worse than the original condition.
Number of subjects	6	8	13	3	0
Percentage of subjects (%)	20	27	43	10	0.00

Safety Information and Adverse Events Results

Safety information (including images taken before and after treatment) was collected throughout the study during each subsequent visit via patient interviews. Additionally, patients were contacted by a study team member within 6 hours after each treatment and asked about their treatment experience. Common treatment responses are side effects that result from treatment which resolve on the order of days. Common treatment responses that persist were defined and categorized as adverse events when assessed by the investigator at the next visit. Subjects were informed of the following potential common treatment responses in the informed consent process: skin will be red and flushed similar to a moderate sunburn, skin tightness and mild sensitivity to the touch, redness, burning, tingling, stinging, itching, and/ or scaling/dryness, edema (swelling), tenderness/discomfort, a possibility of developing an infection (an increase in redness, warmth, itching, or pus formation). Adverse events were assessed by the investigator at each subsequent visit. At the 6-month post-treatment visit, no adverse events persisted.

Safety Endpoint: Common treatment responses (CTRs) reported during the study:

There were 10 out of 30 subjects (33% with 95% CI from 17% to 50%) who completed the trial and had their abdomen treated that experienced common treatment responses. Some subjects experienced more than one CTR. The following CTRs were reported:

Scabbing/peeling: There were 2 out of 30 (7%) subjects who completed the trial and had their abdomen treated who presented scabbing/peeling symptoms that lasted up to 6 days after treatment.

Dryness: There were 4 out of 30 (13%) subjects who completed the trial and had their abdomen treated that presented dryness symptoms that lasted up to 8 days after treatment.

Discomfort: There were 2 out of 30 (7%) subjects who completed the trial and had their abdomen treated that presented discomfort symptoms that lasted up to 2 hours after treatment.

Redness/Swelling: There were 6 out of 30 (20%) subjects who completed the trial and had their abdomen treated that presented redness/swelling symptoms that lasted up to 4 days after treatment.

Adverse Events: There were 2 out of 34 subjects who completed the trial and presented adverse events (hyperpigmentation- one subject Fitzpatrick Skin Type II and one subject Fitzpatrick Skin Type III). The incidence of adverse events (hyperpigmentation) was 6% with 95% CI from 0% to 14% in the 34 subjects that completed the trial. As stated above, at the 90 day after initial treatment visit, 2 subjects (2/34, 6%) reported hyperpigmentation in the area of the treated side of the scar that had persisted since treatment on day 31. However, at the 180 day safety visit, both subjects reported that the hyperpigmentation had resolved. This hyperpigmentation adverse event that resolved within the six month safety period was not unexpected, as similar reports of hyperpigmentation that resolves within six months has been reported in the literature5. No other patient reported any other adverse event and the investigators did not observe any other adverse event when examining the subject as well as the images taken before and after each treatment visit.

Non-Clinical Test Reports

The following tests were performed on the SkinStylus SteriLock® MicroSystem device.

Table 1 Summary of Non-Clinical Performance Testing

Test Completed	Standard
Biocompatibility[A]	
	Cytotoxicity - ISO 10993-5:2009
	Sensitization –ISO 10993-10:2010
	Irritation - lntracutaneous Injection Test GLP - ISO 10993-10:2010
	Acute Systemic Toxicity – Systemic Injection GLP - ISO 10993-11:2017
	Material-Mediated Pyrogenicity ISO 10993
	Metallurgical Analysis – GLP - ASTM E1019-11(Method A)(C/S Analyzer)

Sterilization Validation[B]	Sterilization of Health Care Products – Moist heat ISO 17665-1:2006 Sterilization of Medical Devices ISO 11737-1: 2006 Sterilization of Medical Devices ISO 11737-2: 2009 Sterility and Bacteriostasis/Fungistasis Tests ISO 11737-2: 2009 and USP 71
Reprocessing Validation[B]	ISO 11737-1: 2018 (AAMI TIR-30; 2011; AAMI TIR-12:2004) Cleaning Validation Intermediate-Level Disinfection Validation Autoclave Sterilization Validation
Fluid Ingress Validation[B]	SkinStylus Sterilock Microsystem Leak Testing Report from MicroChem Laboratories
Shelf-life Testing[B]	Standard Test Method for Seal Strength of Flexible Barrier Materials ASTM F88/F88M-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration ASTM F1929-15
	Standard Test Method for Microbial Ranking of Porous Packaging Materials ASTM F1608-16
Electrical Safety and Electromagnetic Compatibility[C]	IEC 60601-1-2 and 60601-1
Depth Penetration Validation[D]	Internal Method - Depth Penetration Report
Needle Reciprocal Rate Validation	Internal Method - Needle Reciprocal Rate Report

[A] Mitigation measure for adverse tissue reaction.

[B] Mitigation measure for cross-contamination and infection.

[C] Mitigation measure for electrical shock or electromagnetic interference with other devices. [D] Mitigation measure for Damage to underlying tissue including nerves and blood vessels, scarring, and hyper/hypopigmentation due to exceeding safe penetration depth or mechanical failure.**

**NOTE: *The proposed device contains NO software*

Summary of Substantial Equivalence

The SkinStylus SteriLock® MicroSystem and the predicate are for similar uses and rely on the same mode of action. Both devices include disposable needle cartridges with design features to mitigate the likelihood of cross-contamination between patients and to prevent needle depth greater than 2.5mm. Both devices also include a redundant safety feature to ensure no fluid enters the motor or housing. The clinical trial conducted on the proposed device confirms that while there may be differences in technology and indications for use, the subject device is as safe and as effective as the predicate.