May 25, 2021

Eclipse MedCorp, LLC
Julie Summerville
Senior Director of Product Management
5916 Stone Creek Drive
The Colony, Texas 75056

Re: K203144
Trade/Device Name: MicroPen EVO™
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: March 1, 2021
Received: March 8, 2021

Dear Julie Summerville:

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 Lixin Liu, Ph.D.
Acting Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203144

Device Name
MicroPen EVO™

Indications for Use *(Describe)*
The Eclipse MicroPen EVO is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years and 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 [This 510(k) Summary is submitted in accordance with 21 CFR Part 807.92(c)]				
Submitted by:	Eclipse Medcorp, LLC. 5916 Stone Creek Drive The Colony, TX 75056	**Contact Person:**	Julie Summerville Senior Dir of Product Management 972-380-2911 x 2405 jsummerville@eclipsemed.com	
Date Prepared:	May 19, 2021			
Trade Name:	MicroPen EVO™			
Common Name:	Powered Microneedling Device			
Product Code; Regulation Name & No:	QAI	Microneedling device for aesthetic use		21 CFR §878.4430
Device Classification:	II			

Device Description:
The Eclipse MicroPen EVO™ is a minimally invasive microneedling device that mechanically creates microscopic punctures in the epidermal and dermal layers of the skin by means of micro-needles in a reciprocating cartridge head. The MicroPen EVO is comprised of a reusable pen body, a sterile, single use microneedling cartridge, a rechargeable battery pack, a battery charger with power supply, and a disposible MicroSleeve sheath. The microneedling cartridge is attached to the pen body and activated with an On/Off button. The depth of needle penetration can be adjusted by the user depending on the condition of the skin being treated. Charging is accomplished by placing the MicroPen EVO pen body or the battery pack on the Charger base.

Indications for Use:
The Eclipse MicroPen EVO is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years and older.

Predicate Device:
The Eclipse MicroPen EVO is predicated against the SkinPen Precision System by Bellus Medical (DEN160029).

Technological Characteristics and Comparison to Predicate
The Eclipse MicroPen EVO has the identical intended use and indications for use as the predicate device and the same or equivalent technological features. A comparison of the subject and predicate device's technological features is presented in the following table.

Technological Characteristics Comparison Chart			
	Subject device Eclipse MicroPen EVO	**Predicate (Primary) SkinPen Precision System**	**Comparison**
510(k)	TBD	DEN160029	NA
Manufacturer	Eclipse MedCorp LLC The Colony, TX, U.S.A.	Bellus Medical, LLC Addison, TX, U.S.A.	NA
Trade Name	MicroPen EVO™	SkinPen® Precision System	NA
Product Code	QAI	QAI	Same
Regulation #	21 CFR Part 878.4430	21 CFR Part 878.4430	Same
Reg Name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Same
Device Class	Class II	Class II	Same
Indication for Use / Intended Use	The Eclipse MicroPen EVO™ is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years and older.	SkinPen® Precision System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years and older.	Same
Intended Users	Rx Only: Licensed healthcare practitioners or individuals directed by practitioners	Rx Only: licensed healthcare practitioners or individuals directed by practitioners	Same

Technological Characteristics Comparison Chart - continued			
Use Location	Face	Face	Same
Power Source (Pen Body)	Rechargeable Li-ion battery	Rechargeable Li-ion battery	Same
Power Source (Battery Charger)	AC Powered	AC Powered	Same
Control Mechanism	Microprocessor; embedded software	Microprocessor; embedded software	Same
Operating Principle	Rotary	Rotary	Same
Single Speed (RPM)	6300-7700	6300 - 7700	Same
Puncture Rate	105-128 stamps/second	105 -128 stamps/second	Same
Microneedling Cartridge	Sterile, Single Use	Sterile, Single Use	Same
No. of Needles	14	14	Same
Needle Gauge	32 Ga	32 Ga	Same
Needle Material	Stainless Steel	Stainless Steel	Same
Needle Shape Geometry	Straight, cylindrical body with a conical tapered, sharp point	Straight, cylindrical body with a conical tapered, sharp point	Same
Arrangement	Needles radially arranged	Needles radially arranged	Same
Needle Spacing	2 mm spacing/3.48 mm^2 per needle	2 mm spacing/3.54 mm^2 per needle	Equivalent: subject device has a slightly smaller total surface area of the hub. No affect to geometry, puncture pattern, needle stamp.
Penetration Depth	1.5 mm (Recommended)	1.5 mm (Recommended)	Same
Max Needle Depth Setting	2.0 mm	2.5 mm	Different: Not significant; treatment depth is 1.5 mm for both devices.
Penetration Depth Selection	9 depth settings; 0 mm to 2.0 mm in 0.25 mm increments	11 depth settings; 0 mm to 2.5 mm in 0.25 mm increments	
Sterility (cartridge)	Ethylene Oxide	Ethylene Oxide	Same
Shelf Life (Cartridge)	2 years	2 years (min)	Same
Barrier: Cross-Contamination	MicroSleeve Sheath (Disposable)	BioSheath (Disposable)	Same

Performance Data

In combination with the general controls of the FD&C Act, the Eclipse MicroPen EVO™ microneedling device for aesthetic use has been subjected to performance testing and adheres to the following special controls and standards:

Motor Speed: Puncture Rate and Needle Penetration Depth Testing
In order to determine if the MicroPen EVO can perform as intended for the recommended 30 minute treatment sessions, maintain accuracy of needle penetration depth and extension, and resist dislodgement and serious deformation of the needles, Eclipse conducted testing under simulated worst-case skin conditions. Worst-case skin was simulated by the use of SynDaver SynTissue plate 10N puncture grade synthetic skin. Normal adult skin exhibits a mean penetration resistance of approximately 2N in areas such as the face and forearm. SynDaver SynTissue with a puncture resistance of 6-8N is representative of callused skin or scar tissue. The 10N SynDaver substrate used in the testing has a penetration force beyond that of thick, calloused human skin or scar tissue, and represents a worst-case load for the device.

Puncture Rate Testing
Eclipse conducted testing to determine if the MicroPen EVO motor can achieve consistent speed and the intended puncture rate within the established tolerance of 7000 RPM ± 10% under worst case skin condition (load) over the duration of the intended operating time. The MicroPen EVO handpieces with attached needling cartridges and battery pack were run continually for 30 minutes (i.e., recommended operating time) under a representative worst-case skin substrate, the SynDaver SynTissue plate 10N penetration grade. The predicate device, SkinPen Precision was also tested so that a side-by-side comparison could be made. Measurements were taken before and after load application, and also at defined intervals while under load to verify the motor is operating at RPMs within the pre-defined specification range of 6300 – 7700 RPMs (7000 ± 10%).

All test articles met the established criteria demonstrating that the MicroPen EVO motor can achieve the intended puncture rate within the established tolerance range of 6300-7700 RPM over the duration of the typical, intended 30 minute operating time. The puncture rate ranged from 6513 to 7164. The results show that the MicroPen EVO motor can perform its intended purpose, even under worst case load, and is substantially equivalent to the predicate device.

Needle Penetration Depth and Extension Accuracy
Eclipse conducted penetration depth testing of the MicroPen EVO microneedling cartridge to determine if, under worst-case conditions, the needle settings meet the specified acceptance criteria by remaining within +/- 0.25 mm of the selected needle depths below 1.50 mm and +0mm/-0.50 mm at selected needles depths of 1.50 mm and above. Worst-case conditions were created by utilizing the synthetic tissue substrate, SynDaver SynTissue plate 10N. This testing evaluated extension accuracy to demonstrate if the maximum possible needle extension does not exceed what has been demonstrated safe in clinical data and literature. The predicate device, the SkinPen Precision, was included for side-by-side comparative purposes.

All MicroPen EVO test articles passed the needle penetration testing coming within +/- 0.25 mm for depth settings up to 1.25 mm; and within +0.00/-0.50 for depth setting between 1.5mm -2.0
mm and no test articles exceeded 2.0 mm Further, none of the needles were dislodged or showed serious deformation at the conclusion of each test. These results demonstrate that the MicroPen EVO can meet the established performance criteria and are substantially equivalent to the predicate device.

Needle Retention
In order to determine if aged MicroPen EVO microneedling cartridges demonstrate adequate retention when subjected to pullout forces.

Needle Retention for Aged Samples Eclipse
To determine if the MicroPen EVO microneedles demonstrate adequate retention under force, nine cartridges and 35 needles were subjected to pullout forces. The microneedles were considered to have passed if the needle retention force is greater than or equal to 110 g (1.08 N) which is the retention force of the SkinPen Precision (predicate).

The needle retention of the all MicroPen EVO test needles (n=35) exceeded the minimum force of 110 g (1.08 N). The results of this test demonstrate that the MicroPen EVO microneedling cartridge needles will perform as intended. The results also demonstrate that MicroPen EVO microneedling cartridge performs better than the predicate device with regard to needle retention and is considered substantially equivalent.

Battery Life
In order to determine if the MicroPen EVO will perform as intended and provide >4 hours of operation under normal use conditions on a single full battery charge, cyclic testing of EVO battery packs was performed under simulated worst-case condition. The 10N SynDaver substrate used in the testing has a penetration force beyond that of thick, calloused human skin or scar tissue, and represents a worst-case load for the device.

Battery Life Testing
In order to establish that the MicroPen EVO will perform as intended and provide >4 hours of operation under normal use conditions on a single full battery charge, cyclic testing was performed under simulated worst case clinical condition using SynDaver Syn Tissue Plate 10N. Each simulated operation cycle consisted of:

1. Installation of a cartridge on the hand piece;
2. 30 minutes of operation against a 10N SynDaver SynTissue plate;
3. 5 minute rest following each cycle to simulate cleaning, disinfection and set-up for next patient).

The activity cycle above was repeated until battery shutdown occurs.

Thirty trials were completed achieving a >95% confidence (95/90). All test articles passed the pre-established acceptance criteria of “at least 8 cycles (four hours) on a single charge” and “no degradation in battery longevity after multiple charges”. The results of the Battery Life Test demonstrated than under worst case clinical conditions, battery run times are significantly higher than required (i.e., Battery Trials 1 and 2: avg 9.38 hours; Battery Trial 3: avg 10.32 hours). These results establish that the Eclipse MicroPen EVO can perform its intended use and supports the substantial equivalence to the predicate device which has similar battery performance requirements.

Use Life
In order to determine if the MicroPen EVO handpiece, charger and battery can perform its intended use for the expected duration of its identified use life of 2000 hours, cyclic testing was performed under simulated worst-case clinical conditions. The 10N SynDaver substrate used in the testing has a penetration force beyond that of thick, calloused human skin or scar tissue, and represents a worst-case load for
the device.

Use Life Testing
In order to establish that the MicroPen EVO handpiece, charger, and battery will perform as intended over its identified useful life, test articles were subjected to simulated procedure cycles to determine the number of cycles each can sustain before degraded device function is observed. The test articles were considered to have passed if it survived at least 2000 hours without physical, mechanical, or visual degradation to the components.

Each simulated operation cycle consisted of:
1. Installation of cartridge assembly onto the MicroPen handpiece;
2. 30 minutes of continuous operation against a 10N SynDaver SynTissue plate (clinical worst case);
3. Following each 30 minute cycle, the handpiece, battery and charger were cleaned and disinfected by the recommended method (i.e., CaviWipes).

The activity cycle above was repeated every 30 minutes for the duration of each day until a total time of 2000 hours of simulated use was achieved. (Cartridge assemblies and batteries were replaced as needed.)

The results of the testing demonstrated that the handpieces, batteries and chargers continued to function for the 2000 hour test and had no observable degradation to finish, seals, mechanical function or labels. All batteries continued to operate beyond 4 hours for the duration of the test. The MicroPen EVO test articles survived the continuous, repeated, simulated use including cleaning and disinfection without degradation, the device is considered to meet the identified use life of 2000 hours.

Cartridge Life
Testing was conducted to determine if the MicroPen EVO microneedling cartridge can continuously perform its intended purpose for the recommended 30 minute treatment sessions. To make this determination, the cartridge was tested under simulated worst-case clinical use to verify if the device can perform consistently under extreme use conditions and show no signs of damage to component form or function. The worst-case scenario was created by the use of aged cartridges (2 year equivalent), 60 minute continuous run times (i.e., twice the recommended) and the use of SynDaver SynTissue plate 10N puncture grade synthetic skin.

EVO Cartridge Reliability Testing
The aged, EVO microneedling cartridges were attached to the hand piece with the needles extended to 2.0 mm and operated at 6300-7700 RPMs against the 10N synthetic tissue for 60 minutes. Test articles were considered to have met acceptance criteria if they completed 60 minutes of continuous use with the applied load and showed no evidence of wear or other damage to the components. The Eclipse MicroPen EVO cartridges met the established acceptance criteria with all nine, test articles operating continuously under load for the entire 60 minutes and were still functional. There were no signs of unacceptable wear, and no observable damage to needles including burrs, hooks, bending, breakage or loss.

The results from the EVO Cartridge Reliability Test demonstrates the ability of the device to perform consistently under extreme conditions of use. This establishes that the MicroPen EVO can perform its intended use under recommended use conditions. Further, these results demonstrate the cartridge's functionality after undergoing to 2 year accelerated shelf-life aging.

This worst-case study demonstrates that the device can perform consistently under extreme conditions of use and its intended purpose throughout the life of the device. These results support the substantial equivalence to the predicate device for intended use performance.

Microbial Ingress Testing
Eclipse has conducted a microbial ingress study utilizing worst case microorganisms including a motile microorganism to determine if the microneedling cartridge and MicroSleeve sheath prevent the ingress of these worst case microorganisms under simulated worst case use. A robust, quantitative method of recovery, incubation and enumeration by colony forming units (CFUs) was employed.

Validation of Ingress Protection of a Microneedling Device
Eclipse conducted ingress testing utilizing worst-case motile microorganisms and simulated worst case use. The microorganisms used are as follows:
•*Staphylococcus aureus* •*Klebsiella pneumoniae*
•*Pseudomonas aeruginosa* •*Escherichia coli (motile)*

Fully assembled MicroPen EVO test units, with MicroSleeve sheaths and aged (2 year equivalent) microneedling cartridges were operated in the presence of the worst-case microorganisms identified above. Aged cartridges were used to demonstrate consistent performance throughout the labeled 2 year shelf life. The test article handpieces (pen bodies) were handled with a gloved hand to which a 10.0 µL aliquot of inoculum had been applied. The test units were turned on, and the cartridge tips were moved over the inoculum placed in a sterile petri dish. To ensure coverage and the greatest ingress challenge, the cartridge tip was rotated and maneuvered over multiple angles to allow the inoculum to drip into the cartridge. The test articles continued to run for 60 minutes – a time twice the recommended treatment session.

A robust, quantitative method of recovery, incubation and enumeration of CFUs was employed to determine the effectiveness of the ingress protection. The results of this study demonstrate the MicroSleeve Protective Sheath and microneedling cartridge for the MicroPen EVO provide effective protection against the ingress of fluid, and aid in the mitigation of cross contamination. These results also support substantial equivalency to the predicate device in performance.

Suction Testing
Testing was performed to determine if the MicroPen EVO would create suction on human skin receiving treatment during device operation. To make this determination, Eclipse performed simulated use on human skin to observe if there were visible signs of suction (e.g., red marks) after 1 minute settings representing the minimum and maximum piston extension limits.

Suction Prevention Testing
Eclipse conducted simulated use of the MicroPen EVO with a modified cartridge assembly on an anterior human forearm. The microneedling cartridge test articles had the needles removed to render 'dummy pistons' that would simulate potential suction without needle penetration. The test cartridges were attached to an EVO handpiece and set to both 0.0 and 2.0mm, representing the minimum and maximum extension limits of the piston respectively. The tip of the cartridge was placed on the anterior forearm while the device was turned on and held in place for 1 minute. This was repeated at both 0.0 and 2.0 settings with all nine test cartridges. The results showed no evidence of suction on the skin after 1 minute of simulated use at minimum and maximum extension limits. The results of this testing demonstrate the needle cartridge design prevents suction during normal use and supports substantial equivalent to the predicate device subjected to similar performance testing.

Cleaning and Disinfection
The handpiece test units were soiled by placing a clean glove onto a dish with artificial test soil (ATS) with 20% defibrinated bovine blood. The entire surface of the palm and fingers were coated. The device was then placed in the gloved hand and soiled by aggressively handling the device, moving around to ensure all surfaces of the device are contacted. A cotton swab was dipped in the ATS and used to force the test soil into all mated areas, cracks, crevasses and seams. This included the saddle and gear, switch seal, and belly seal. The battery pack test units and charger test units were independently soiled by placing a clean glove onto a dish with artificial test soil (ATS) with 20% defibrinated bovine blood. The entire surface of the palm and fingers were coated. The battery and charger were then placed in the gloved hand and soiled by aggressively handling the device, moving around to ensure all surfaces of the battery and the charger were contacted including the battery seal. The test soil represents a worst-case challenge for cleaning and simulates clinical blood constituents including its viscosity and drying characteristics on critical areas and without the use of the provided MicroSleeve Protective Sheath. To further simulate worst-case cleaning extremes, testing was performed on freshly soiled (wet) devices and also on soiled devices allowed to dry for 24 hours. This is to simulate worst-case extremes on a device

that has been cleaned immediately after use and a device that has been left uncleaned for 24 hours. This combination of worst-case soiling and worst-case simulated-use soiling presents the appropriate challenge, given a typical procedure should only produce a small amount of pin-point bleeding.

For the handpiece, intermediate-level disinfection validation shows a 6-log reduction of common vegetative microorganisms (list below and tested individually), as well as a 3-log reduction of mycobacterium. The battery pack and charger were soiled, cleaned and disinfected with the same procedure as the handpiece, however they were validated for low-level disinfection (6-log reduction of common vegetative organisms but did not include mycobacterium.) This new testing includes the following organisms.

Gram Negative (-)	Gram Positive(+)	Mycobacterium
Pseudomonas aeruginosa	Staphylococcus aureus	Mycobacterium terrae
Escherichia coli		
Klebsiella pneumoniae		

Sterilization and Shelf Life

- Ethylene oxide sterilization per ISO 11135-2014; ISO11737-1:2018; ISO 11737-2: 2009; ISO 10993-7:2008
- Sterilization, Shelf Life/Package Integrity in accordance with the following standards: ASTM-F1980 Std Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices; ASTM-F1886-2016 Std Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection; ASTM-F1929-2015 Std Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration; ASTM-F88 Std Test Method for Seal Strength of Flexible Barrier Materials; ANSI/AAMI/ISO 11607-1: 2006(R) 2010/ A1-2014, Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier System and Packaging Systems; ASTM F2096-11 (2019) Std Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test); ASTM F88/F88M-15 -Std Test Method for Seal Strength of Flexible Barrier Materials. Real time aging studies are being conducted at the extremes of storage limits, ambient temperature, and cycling between the 3 conditioning temperatures. Visual sampling and verification is conducted at 6 month intervals, while seal strength, dye migration and performance testing and cartridge reliability test are performed at 1 year intervals up to the 2 year stated shelf life.

Biocompatibility.

- The following tests were performed on the final, finished microneedling cartridge : (1) Cytotoxicity (ISO 10993-5:2009); (2) Sensitization and (3) Irritation/Intracutaneous Reactivity (ISO 10993-10: 2010); (4) Acute Systemic Toxicity (ISO 10993-11:2017); (5) Material Mediated Pyrogenicity (ISO 10993-11:2017, USP 41 NF 36:2018, <151> Pyrogen Test. The results of these tests demonstrated the device to be biocompatible with no evidence of material mediated pyrogenicity.

Electrical Safety and Electromagnetic Compatibility:

- IEC- 60601-1:2005 + A1: 2012 – Medical electrical equipment–Part 1: General Requirements for Basic Safety and Essential Performance; EN/IEC 60601-1-2: 2015 /IEC 60601-1-2: 2014–Medical electrical equipment–Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirement and tests.
- Software: ISO 62304:2006

Substantial Equivalence: The MicroPen EVO is substantially equivalent to the Bellus Medical SkinPen® Precision System predicate device. The devices are under the same product code (QAI), both have the same intended use/ indication for use, same number of needles, gauge, shape and arrangement, same

material, recommended penetration depth, speed, puncture rate and sterilization method. The only technological differences are the maximum needle depth setting: the MicroPen EVO is 0.5 mm shorter (2.0 mm) than the predicate (2.5 mm); and the penetration depth selection: the MicroPen EVO has 9 depth settings (0-2.0 mm in 0.25 mm increments) and the predicate device has 11 depth settings (0-2.5 mm in 0.25 mm increments). These differences are minor and are not significant since both devices recommend the same treatment depth (1.5 mm). There is a small and insignificant difference between the subject and predicate in total surface area of the hub, however the needle spacing is the same (2 mm) and there is no effect on geometry, puncture pattern, needle stamp. These minor differences do not raise different questions of safety and effectiveness. Further, the results of performance testing support substantial equivalence of the Eclipse MicroPen EVO to the predicate device.

Conclusion

The Eclipse MicroPen EVO is considered to be substantially equivalent to the predicate device based on the intended use, technological characteristics, and the results of device testing submitted.