December 13, 2022

CC Biotechnology Corporation
Judy Cheng
Regulatory Associate
No. 68, Gongye 5th Rd., Annan Dist.
Tainan, 709015
Taiwan

Re: K214004
Trade/Device Name: CCBIO ASCPO Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 18, 2022
Received: November 21, 2022

Dear Judy Cheng:

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,

CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K214004

Device Name
CCBIO ASCPO Needle

Indications for Use *(Describe)*
The ASCPO Needle is intended for use in the subcutaneous injection of fluid for medical purpose. The ASCPO Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety sheath can be automatically activated to cover the needle and locked immediately after use to minimize risk of accidental needlestick.

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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This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at June 06, 2017.

The assigned 510(k) number is: K214004

1. Submitter's Identifications:

Applicant' Name:	CC Biotechnology Corporation
Address:	No. 68, Gongye 5th Rd., Annan Dist., Tainan City 709015, Taiwan (R.O.C).
Telephone:	886-6-3845868
Fax:	886-6-3843968
Official Correspondent:	Edgar Yeh
Date Prepared:	November 18, 2022

2. Name of the Device:

Trade/Proprietary Name:	CCBIO ASCPO Needle, model BA-2001
Common Name:	Single Lumen Hypodermic Needle
Classification Regulations:	Needle, Hypodermic, Single Lumen Class II, 21 CFR 880.5570
Product Code:	FMI
Classification Panel:	General hospital and personal use devices

3. Device Description:

The ASCPO Needle is a single lumen needle intended to inject fluids subcutaneously. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe.

The ASCPO Needle is intended for use in the subcutaneous injection of fluid for medical purpose. The ASCPO Needle is compatible for use with standard luer-slip and luer-lock syringes. Additionally, after withdrawal of the needle from the body, the needle safety sheath can be automatically activated to cover the needle and locked immediately after use to minimize risk of accidental needlestick.

4. Intended Use:

The ASCPO Needle is intended for use in the subcutaneous injection of fluid for medical purpose, and used for adults only. The ASCPO Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety sheath can be automatically activated to cover the needle and locked immediately after use to minimize risk of accidental needlestick.

5. Information of the 510(k) Cleared Device (Predicate Device):
   - BD Eclipse™ Needle (K100209).

The reason for choosing BD Eclipse™ Needle (K100209) as the SE predicate model is because that the new ASCPO Needle and BD Eclipse™ Needle (K100209) have the same claim of indication for use for which both two models are claimed for prescription use of general purpose injection, and are compatible for use with standard luer-slip and luer-lock syringes.

6. Overall comparison table:

ATTRIBUTE /	ASCPO Needle	BD Eclipse™ Hypodermic	Substantial Equivalence(SE)

CHARACTERISTIC	(Submitted Product)	Needle **(Predicate Device)**	Comparison
'K" numbers	K214004	K100209	No Comment
Manufacturer	CC Biotechnology	Becton Dickison	No Comment
Intended Use	For use in the subcutaneous injection of fluid for medical purpose, and used for adults. The ASCPO Needle is compatible for use with standard luer slip and luer lock syringes.	Used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Needle with SmartSlip™ Technology is compatible for use with standard luer-slip and luer-lock syringes.	Similar, since they were designed for general injection and are compatible for use with luer-slip and luer-lock syringes.
Operating Principle	This device is single lumen needle intended to inject fluids subcutaneously and it has a passive sharps protection feature that covers the cannula immediately and permanently after use	Composed of a typical hypodermic needle with a one-piece hub/adapter and pivoting cover that is connected to the adapter. When assemble the plastic clip into the hub, the clip ensures that the needle is attached to a luer slip syringe with sufficient force by the user. The pivoting safety cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint making the product safe for disposal	Different but not render non-substantial equivalence, since new device was tested and demonstrated to comply with FDA SIP Guidance and ISO 23908 standard.
SIP Feature	passive sharps protection feature that covers the cannula immediately and permanently after use	The pivoting safety cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint making the product safe for disposal.	Different but not render non-substantial equivalence, since new device was tested and demonstrated to comply with FDA SIP Guidance and ISO 23908 standard.
Connector type	Luer lock and luer slip	Luer lock and luer slip	Similar
Color coding	Per ISO 6009	Per ISO 6009	Similar
Tip configuration	triple sharpened, non-coring	triple sharpened, non-coring	Similar
Materials	Hub: Styrene Butadiene Copolymer Cap: Polyoxymethylene	Hub: Polypropylene Cannula: Stainless Steel Cannula Lubricant: Silicone	Different but no significant impact on SE comparison.

	Cannula: Stainless Steel Cannula Lubricant: Silicone Needle/Safety Shield: Polyoxymethylene Adhesive: UV Acrylic	Needle/Safety Shield: Polypropylene	
Specification	Needle Length: 1/2" Needle Gauge: 27 Gauge	Needle Length: 1/2"- 1 ½ Needle Gauge: 18-30 Gauge Bevel: Regular, Short, Intradermal	Different but no significant impact on SE comparison.
Packaging	Sterilization pouch Shelf carton Case carton	Sterilization pouch Shelf carton Case carton	Different but no significant impact on SE comparison.
Functional testing	ISO 23908:2011 ISO 7864:2016 ISO 9626:2016 ISO 80369-7:2021 Measuring the penetration force: Meet internal CCBio specification	Hub/Needle Bond Strength: Met internal BD specification Needle Penetration Test: Met internal BD specification Needle Shield Removal Forces: Met internal BD specification Leak Testing: Per ISO 594-2	Different but no significant impact on SE comparison, since new device was tested and demonstrated to comply with the related FDA recognized ISO standards
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Similar
SAL Level	SAL 10^{-6}	SAL 10^{-6}	Similar
Shelf Life	3 Years	5 Years	Different but no significant impact on SE comparison.
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Similar
Used as Rx or OTC	Rx(Prescription Use)	Rx(Prescription Use)	Similar

7. Comparison to the 510(k) Cleared Device (Predicate Device):
As per reasons for choosing BD Eclipse™ Needle (K100209), we conducted further comparison as follows：

- **Comparison of Indication for use.**

Based on this, the comparison for the indication for use between new and predicate model was provided hereafter.

Model	**ASCPO Needle (Submitted Product)**	**BD Eclipse™ Hypodermic Needle (Predicate Device)**
510(k) No.	**K214004**	**K100209**
Prescription or OTC	**Prescription**	**Prescription**

Indication for use	**For use in the subcutaneous injection of fluid for medical purpose. The ASCPO Needle is compatible for use with standard luer slip and luer lock syringes.**	**Used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Needle with SmartSlip™ Technology is compatible for use with standard luer slip and luer lock syringes.**
FDA product code	**FMI**	**FMI**

Brief comparison result:

Based on comparison information as above mentioned, it is very clear that the "Indication for Use" for the new devices and 510(k) cleared devices are considered as "Substantially Equivalent", even though the Indication for use statement is not completely identical. The determination of substantial equivalence in indication for use is because of the following reasons:

1> Both these two models were designed for "general purpose injection"

2> Both these two models were claimed for "Prescription Use"

3> Both these two models were classified as FDA "FMI" product code.

4> Both these two models were compatible for use with standard luer slip and luer lock syringes.

- **Comparison of the Technology Aspect.**

The comparison for the technology aspect between new and predicate model was as the following table.

Model	ASCPO Needle (Submitted Product)	BD Eclipse™ Hypodermic Needle (Predicate Device)
510(k) No.	K214004	K100209
Operation principle	This device is single lumen needle intended to inject fluids subcutaneously and it has a passive sharps protection feature that covers the cannula immediately and permanently after use	When assemble the plastic clip into the hub, the clip ensures that the needle is attached to a luer slip syringe with sufficient force by the user. The pivoting safety cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint making the product safe for disposal
SIP feature	passive sharps protection feature that covers the cannula immediately and permanently after use	The pivoting safety cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint making the product safe for disposal.
Compliance standard	ISO 23908 & FDA guidance for SIP	ISO 23908 & FDA guidance for SIP

Brief comparison result:

In the actual device construction, there may be some in the SIP mechanism, namely K100209 is an activate type safety needle, but ASCPO Needle is a passive type safety needle. However, the SIP feature for both models was designed according to ISO 23908 standard and FDA Specific guidance for SIP feature. Therefore, we concluded that the ASCPO Needle is substantially equivalent with BD Eclipse™ Hypodermic needle(K100209) in the main technology aspect.

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of the devices is as follows:

Biocompatibility has been tested according to the requirements of ISO10993-1. In consideration of the International Standard ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing, following biocompatibility tests were performed on the final finished device to evaluate: Cytotoxicity, Sensitization, Intracutaneous Irritation, Systemic Toxicity and Hemolysis.

The sterility of the ASCPO Needle is assured by using a validated sterilization method which complies with the requirements of the FDA Recognized Consensus Standard: ISO 11135:2014, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. Ethylene oxide (EO) and Ethylene Chlorohydrin (ECH) residuals were tested according to ISO 10993-7: 2008 and met the acceptance criteria.

Meanwhile ASCPO Needle was tested to demonstrate to comply with the following standards:
- ISO 23908:2016 “Sharp Injury protection- Requirements and test methods - SIP features for single use hypodermic needles,
- ISO 7864:2016 “Requirements and test methods Sterile hypodermic needles for single use”,
- ISO 9626:2016 “Stainless steel needle tubing for the manufacture of medical devices.
- ISO 80369-7:2021 “Small-bore connectors for liquids and gases in healthcare applications, Part 7: Connectors for intravascular or hypodermic applications.”
- ISO 10993-10: 2010 “Biological evaluation of medical devices - Part 10: Tests for skin Sensitization.”
- ISO 10993-11: 2017 “Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.”
- ISO 10993-5: 2009 “Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.”
- ISO 10993-7: 2008 “Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.”
- USP<151>: 2020 “Pyrogen test.”
- ISO 11135: 2014 “Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.”
- ISO 11607-1: 2019 “Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.”
- ASTM D4169-16 “Standard Practice for Performance Testing of Shipping Containers and Systems.”
- USP 788” Particulate Matter in Injections.”

The tests completed under each standard as shown in the table below:

Standard	Test Performed
ISO 7864: 2016	Cleanliness
	Limits for acidity or alkalinity
	Limits for extractable metals
	Size designation
	Color coding
	Conical fitting (per ISO 80369-7: 2021)
	Effective needle length
	Lubricant
	Needle point

	Bond between hub and needle tube
	Patency of lumen
	Sharps injury protection (per ISO 23908: 2011)
	Sterility
	Biocompatibility
ISO 9626: 2016	Surface finish and visual appearance
	Cleanliness
	Limits for acidity or alkalinity
	Stiffness
	Resistance to breakage
	Resistance to corrosion
ISO 80369-7: 2021	Leakage by pressure decay
	Sub-atmospheric pressure air leakage
	Stress cracking
	Resistance to separation from axial load
	Resistance to separation from unscrewing
	Resistance to overriding
ISO 23908: 2011	Testing access to the sharp in safe mode
	Security of safe mode protection
	Challenging the device in safe mode
	Testing simulated clinical use
ISO 10993-10: 2010	Tests for skin sensitization
ASTM F756-17	Standard Practice for Assessment of Hemolytic Properties of Materials
ISO 10993-11: 2017	Tests for systemic toxicity
ISO 10993-5: 2009	Tests for in vitro cytotoxicity
USP<151>: 2020	Pyrogen test
ISO 11135: 2014	Validation and routine control of a sterilization process for medical devices
ISO 10993-7: 2008	Ethylene oxide sterilization residuals
ISO 11607-1	Tests for materials, sterile barrier systems and packaging systems.
ASTM D4169-22	Performance Testing of Shipping Containers and Systems.
USP 788	Particulate Test

Additionally, the shelf-life validation reports were also included in the submission to demonstrate that the ASCPO Needle is adequate for use as claimed 3 years life time.

Discussion: The Compliance to applicable voluntary standards as above mentioned indicates that the new device in this submission used the same standards as that of predicate device.

Therefore; we consider that the compliance of standards included in our submission is adequate for the determination of substantial equivalence.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device is as follows:

The Simulated Clinical Use Study and Human Factor Study were conducted and performed according to the method as recommended in the FDA specific guidance, entitle "Medical Devices with Sharps Injury Preventive Features".

For the Simulated Clinical Use Testing, 500 simulated injections were completed. The testing data indicated that no any failure was observed in a test run of 500 devices, so it would be 97.5% confident that the true failure rate was no higher than 0.7% and 99.5% confident that it was no higher than 1.1% based on the statistical data as presented in the Simulated Clinical Use Test Report. This testing result complies with the acceptance requirement as specified in the FDA guidance for SIP features as above mentioned.

For the Hunan Factor Study, TDICT SIP Evaluation Forms were completed by 5 enrolled qualified evaluators according to the validation study protocol. The investigation results demonstrated that the ASCPO Needle meets all the operation and usability requirements as recommended in TDICT SIP Evaluation plan, the labeling is effective and strongly likely to be read, that the user interface is well understood by potential user without prior education, and that it provides sufficient information and/or is designed as expected by end-users for a safe and effective use of the device.

10. Summary for the technology comparison.

Based on the evidence conducted and completed for the non-clinical and clinical test validation activities as above mentioned, we draw up the summary that the ASCPO Needle was designed, manufactured, verified and validated to comply with the main technology requirements as specified in the specific FDA guidance, entitle "Medical Devices with Sharps Injury Preventive Features" as well as the product related FDA recognized standards namely ISO 10993-1 & related biocompatibility test standards, ISO 11135, ISO 23908, ISO 7864, ISO 9626, ISO 80369-7, ISO 10993-10, ISO 10993-11, ISO 10993-5, ISO 10993-7, USP<151>, ISO 11135, ISO 11607-1, ASTM D4169-22 and USP 788.

Therefore, we concluded that the ASCPO Needle new device is substantially equivalent to the predicate device in the technology aspect.

11. Conclusions

The details of assessments and testing as above mentioned were included in the whole package of this 510(k) submission. Through the detailed assessments and testing as mentioned above, we believe we have provided sufficient information to prove “SE” (Substantial Equivalence) for the ASCPO Needle new device and the chosen predicate devices as mentioned in this 510(k) summary.