December 21, 2022

V3bio Sdn. Bhd
% Miriam Walls
President and CEO
xFDA
PO Box 4821
McLean, Virginia 22103

Re: K220286
Trade/Device Name: ELECTROCYN soma
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 30, 2022
Received: February 1, 2022

Dear Miriam Walls:

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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
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)*
K220586

Device Name
ELECTROCYN soma

Indications for Use *(Describe)*

Rx Indications:

Under the supervision of a healthcare professional, ELECTROCYN soma is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic wounds including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin and diabetic foot ulcers. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC Indications:

ELECTROCYN soma is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

1. **Date of Preparation:** November 22, 2022

2. **Sponsor Identification**

V3bio Sdn. Bhd,
No. 18, Jalan Cassia Selatan 3/1,
Taman Perindustrian Batu Kawan,
14100 Bandar Cassia,
Penang, Malaysia

Contact Person: Shudipta Choudhury
Tel: 4-5886993
Email: s.choudhury@v3bio.com

3. **Designated Submission**

Miriam Walls (Primary Contact Person)

xFDA – FDA Consulting for Drugs, Biologics and Medical Devices

PO Box 4821
McLean, Virginia 22103-4821
Phone: 703-966-1100

Email: mwall@xfda.com

4. **Subject Device**

Name of Device: ELECTROCYN soma
Common Name: Wound Cleanser
Classification Name: Dressing, Wound, Drug
Class: Unclassified, Pre-amendment status
Product Code: FRO

5. **Identification of Predicate Device510(k) Number:**

K172622 - Sonoma Pharmaceuticals, Inc.
Name of Device: Microcyn Antimicrobial Skin and Wound Cleanser
Common or Usual Name: Wound Cleanser
Classification Name: Solution, Saline Wound Dressing Regulatory
Class: Unclassified, Pre-amendment status
Product Code: FRO

6. Device Description

ELECTROCYN soma contains purified water - 99.9%, hypochlorous acid (HOCl) + sodium hypochlorite (NaOCl) + sodium chloride (NaCl) ≈ 0.1% and packed in HDPE bottles.

Product Overview
ELECTROCYN soma is a medical devices under category of wound wash and irrigation solution. The solution contains 99.9% purified water and with combined percentage of not more than 0.1% of Hypochlorous acid (HOCl) + Sodium hypochlorite (NaOCl) + sodium chloride (NaCl) which are produced by electrolysis technology with the use of purified water and purified salt.

HOCl acts as preservative for the solution to prevent microbial growth within the solution.

Mode of Action
The primary intention of the ELECTROCYN soma solution is for mechanical debridement, irrigation, and moistening. The mechanical action of irrigating and debriding would assist in removing dead, damaged and contaminated tissues on and around the wound.

Product Range

Name as Per Device Label	Product Description
Electrocyn soma	Electrocyn soma, 100 mL spray mist
Electrocyn soma	Electrocyn soma, 250 mL, spray mist
Electrocyn soma	Electrocyn soma, 250 mL, cap closure
Electrocyn soma	Electrocyn soma, 500 mL, cap closure

Summary of Packaging Material and Configuration

Product Description	Bottle Type	Stopper	Capping Type	Packaging Box* **single bottle box*
Electrocyn soma, 100 mL spray mist	100mL HDPE Bottle	Not Available	Spray Mist	Available
Electrocyn soma, 250 mL, spray mist	250mL HDPE Bottle	Not Available	Spray Mist	Not Available
Electrocyn soma, 250 mL, cap closure	250mL HDPE Bottle	Available	Cap Closure	Not Available
Electrocyn soma, 500 mL, cap closure	500mL HDPE Bottle	Available	Cap closure	Not Available

7. Indications For Use

Rx Indications:

Under the supervision of a healthcare professional, ELECTROCYN soma is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic wounds including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin and diabetic foot ulcers. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC Indications:

ELECTROCYN soma is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

8. Substantially Equivalent (SE) Comparison

Item	Proposed Device	Predicate Device (K172622)	Comparison
Product name	ELECTROCYN soma	Microcyn Antimicrobial Skin and Wound Cleanser	
Product code	FRO	FRO	Same
Prescription (Rx)/Over the Counter (OTC)	OTC and Rx	OTC and Rx	Same
Indications for use	**Rx Indications**: Under the supervision of a healthcare professional, ELECTROCYN soma is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic wounds including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin and diabetic foot ulcers. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds. **OTC Indications:** ELECTROCYN soma is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	**Rx Indications:** Under the supervision of a healthcare professional, Microcyn™ Antimicrobial Skin and Wound Cleanser is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, firstand second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds. **OTC Indications:** Microcyn ™ Antimicrobial Skin and Wound Cleanser is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	Same
Technology	Ingredients: Water, Sodium Chloride, Hypochlorous Acid, Sodium Hypochlorite	Ingredients: Water, Sodium Chloride, Hypochlorous Acid, Sodium Hypochlorite	Same
Sterility Claim	Non-Sterile	Non-Sterile	Same

Item	Proposed Device	Predicate Device (K172622)	Comparison
Mechanism of Action	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the wound or device.	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the wound or device.	Same
Delivery System	Aqueous Solution	Aqueous Solution	Same

9. Non-Clinical Testing

Biocompatibility Testing

Biocompatibility on ELECTROCYN soma was performed in regards with ISO 10993 Biological Evaluation of Medical Devices, which aim to evaluate the safety and protection of humans from potential biological risk arising from the use of medical device. Biocompatibility test was selected based on Table 2 in Annex A (ISO 10993-1). From the table, under nature of body contact, ELECTROCYN soma falls under the category of surface device. In contact duration category, ELECTROCYN soma falls under B- prolonged (> 24h to 30d).

REPORT TITLE	REFERENCE	RESULT
Acute Inhalation Toxicity Study of Eectrocyn in Sprague Dawley Rats	OECD Guideline No. 403	No related clinical signs of toxicity and mortality observed. Electrocyn is classified as relatively low acute toxicity.
Skin Sensitization Study of Electrocyn in Guinea Pigs by Maximization Test	ISO 10993-10: 2013	No gross pathological changes observed in tested animals. Electrocyn is found to be "non-sensitizer" to the skin.
Acute Ocular Irritation Test of Electrocyn In New Zealand White Rabbits	ISO 10993-10: 2013	No gross pathological changes observed in any tested animals. Electrocyn is concluded as "non-irritant" to the eyes.
Vaginal irritation Test of Electrocyn in New Zealand White Rabbits	ISO 10993-10: 2013	The irritation index was found to be 0.00 on tested animal. Electrocyn is considered as "non-irritant" to the vagina.
In vitro Cytotoxicity Study of Electrocyn By Agarose Overlay Method	ISO 10993-5: 2009	No reactivity was observed on the fibroblast cells. Electrocyn is 'non-cytotoxic" to the subconfluent monolayer of mouse fibroblast cells.
In vitro Mammalian Cell Micronucleus Test of Electrocyn In Human Lymphocytes	OECD Guideline No. 487	Electrocyn is non clastogenic and non anuegenic in cultured human lymphocytes in short and long term treatments.
Acute Oral Toxicity Study of Electrocyn In Sparague Dawley Rats	OECD Guideline No. 423	No clinical signs of toxicity. No gross pathological changes were observed in all tested animals. Electrocyn is classified as relatively low acute toxicity.
Skin Irritation Test of Electrocyn In New Zealand White Rabbits	ISO 10993-10: 2013	No evidence of irritation of Electrocyn when applied topically on tested animals. Electrocyn is classified as "negligible irritant".

REPORT TITLE	REFERENCE	RESULT
Intracutaneous Reactivity Test of Electrocyn In New Zealand White Rabbits	ISO 10993-10: 2013	None of the animals revealed skin reactions. Electrocyn is proved as "non-irritant" to the skin.
Acute Dermal Toxicity Study of Electrocyn In Sprague Dawley	OECD Guideline No. 402	No clinical signs of toxicity and mortality, skin reactions, and gross pathological changes were observed. Electrocyn is classified as relatively low acute toxicity.
Acute Systemic Toxicity Study of Electrocyn soma In Albino Mice	ISO 10993-11:2017	Electrocyn soma when administered to Swiss Albino Mice through intravenous route at a dose volume of 50 ml/kg body weight did not reveal any systemic toxicity
Material Mediated Pyrogen Test of Electrocyn soma in New Zealand White Rabbits	USP General Chapter <151>	Electrocyn soma evaluated for pyrogen test in New Zealand White Rabbits is non-pyrogenic
Antimicrobial Effectiveness Testing	USP <51>	Bacteria - NLT 2.0 log reduction from the initial count at 1 days, and no increase from the 14 days to 28 days. Yeast – No increase from the initial calculated count at 12 and 28days.

Non-Clinical Performance Testing

TEST PERFORMED	DEVICE DESCRIPTION/ SAMPLE SIZE	TEST METHOD/ APPLICABLE STANDARDS	SPECIFICATION COMPLIANCE
1. Composition analysis	Finished product	Titration	Comply
2. Bioburden analysis	Finished product	ISO 11737-1:2018	Comply
3. Antimicrobial Efficiency	Finished product	ASTM E2315	Comply
4. Stability Study – Accelerated Aging	Finished product, 41 bottles	ICH Harmonised Tripartite Guideline – Stability Testing of New Drug Substances and Products Q1A (R2)	Comply
5. Packaging Validation of Transportation Testing	3 cartons with 24 bottles x 500ml Electrocyn soma	ASTM D 276	Comply

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

ELECTROCYN soma is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Microcyn Antimicrobial Skin and Wound Cleanser manufactured by Sonoma Pharmaceuticals, Inc (K172622). Therefore, the ELECTROCYN soma is substantially equivalent to the predicate device.