March 11, 2020

Arch Therapeutics, Inc.
Terrence Norchi
President, Chief Executive Officer
235 Walnut Street, suite 6
Framingham, Massachusetts 01702

Re: K190129
Trade/Device Name: AC5 Topical Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 11, 2020
Received: March 11, 2020

Dear Terrence Norchi:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190129

Device Name
AC5 Topical Gel

Indications for Use *(Describe)*
Under the supervision of a health care professional, AC5 Topical Gel is a topical dressing used for the management of partial and full- thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

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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510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR 807.92.

Date prepared: February 27, 2020

The assigned 510(k) number is: K190129

Applicant Arch Therapeutics, Inc.

Company Contact

Terrence Norchi, MD
235 Walnut Street, Suite 6
Framingham, MA 01702
email: info@archtherapeutics.com
Phone: (617) 431-2316

Product

Trade name: AC5™ Topical Gel

Common name: Wound Dressing

Classification: Unclassified

Product Code: FRO

11.1 Predicate/ Legally Marketed Devices

Information about the device to which substantial equivalence is claimed:

Manufacturer: Arch Therapeutics, Inc
Device Trade Name: AC5™ Topical Gel
510 (k): K182681

11.2 Device Description

AC5 Topical Gel is configured as a package containing one vial of synthetic self-assembling peptide, one vial of diluent (Sterile Water for Injection, USP), one syringe, one needle, two blunt fill needle applicators and two Alcohol Prep pads. AC5 is biocompatible. The diluent (Sterile Water for Injection, USP) is sterile and non-pyrogenic. AC5 is to be prepared by reconstitution of the lyophilized peptide in Sterile Water for Injection, USP. The reconstituted peptide solution is acidic (pH 2.3 ± 0.7).

11.3 Device Components

The vial containing AC5 peptide is sterilized by gamma irradiation. All components of AC5 Topical Gel are sterile and packaged into a kit in a controlled environment with IFU and Labels.

A list of the components, description and quantity is listed in Table 11.3-1.

Table 11.3-1. AC5 Topical Gel Components, Description and Quantity

Component	Description	Quantity
Peptide Vial	Glass 3 mL vial containing lyophilized peptide	1 vial, 45 mg ± 5 mg
Diluent Vial	Glass 6 mL vial containing Sterile Water for Injection USP	1 vial, 5 mL
Reconstitution and Application Syringe	Sterile 3 mL syringe with Luer-Lok™ tip	1 syringe
Needle	Sterile 18G X 1.5 inch	1 needle
Blunt applicator	Sterile 18G X 1.5 inch	2 blunt applicators
Alcohol Prep pad wipes	1” X 1 ¼” folded, saturated with 70% isopropyl alcohol	2 pads

11.4 Indications for Use/ Intended Use

Under the supervision of a health care professional, AC5 Topical Gel is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

Please note: Arch Therapeutics is seeking prescription use indications.

11.5 Comparison of Technological Characteristics

A comparison of the technological characteristics of AC5 Topical gel and the above selected predicate device given a addition in manufacturer of the peptide is provided in Table 11.5-1

Table 11.5-1. Comparison of Technological Characteristics AC5 Topical Gel and Predicate Device

Device Name	AC5™ Topical Gel	AC5™ Topical Gel
Manufacturer	Arch Therapeutics, Inc.	Arch Therapeutics, Inc.
510(k)	K190129	K182681
Product code	FRO	FRO
Indication for use	Under the supervision of a health care professional, AC5 Topical Gel is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.	Under the supervision of a health care professional, AC5 Topical Gel is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.
Composition	AC5 Topical Gel is a sterile gel composed of a synthetic peptide and sterile water for injection. It is provided in a vial containing lyophilized peptide, which must be reconstituted using sterile water prior to use. AC5 is completely non-animal and non-plant derived, and contains no preservatives.	AC5 Topical Gel is a sterile gel composed of a synthetic peptide and sterile water for injection. It is provided in a vial containing lyophilized peptide, which must be reconstituted using sterile water prior to use. AC5 is completely non-animal and non-plant derived, and contains no preservatives.
Mechanism of Operation	AC5 forms a moist wound environment that is supportive of the healing process and allows non-traumatic removal of the secondary dressing without damaging newly formed tissue.	AC5 forms a moist wound environment that is supportive of the healing process and allows non-traumatic removal of the secondary dressing without damaging newly formed tissue.
Labeling	Sterile, Single Use Only Prescription Use Only	Sterile, Single Use Only Prescription Use Only

11.6 Performance

Risks to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

The recommended biocompatibility tests for this category of devices were identified from the Guidance for Industry and Food and Drug Administration Staff, issued on June 16, 2016 entitled *Use of International Standard ISO-10993, Biological evaluation of medical devices Part 1 Evaluation and testing within a risk management process*. The testing was conducted in full accordance with the Food and Drug Administration's Good Laboratory Practice regulations (21 CFR Part 58). Specifically, AC5 was evaluated for cytotoxicity, sensitization, irritation (animal irritation with abraded skin and animal intracutaneous reactivity), acute systemic toxicity, pyrogenicity (endotoxin and material mediated), implantation and subchronic/subacute toxicity. AC5 passed all tests conducted.

11.7 Substantial Equivalence

Following the examination of all the above-mentioned information, we believe that AC5 Topical Gel is substantially equivalent to the selected predicate device in terms of design, materials, intended use, and there are not different questions of safety and effectiveness.