August 20, 2024

Okapi Medical LLC dba Resivant Medical
Tom Stephens
Sr. Director, Regulatory Affairs and Quality Assurance
526 S. Main St. Suite 124M
Akron, Ohio 44311

Re: K234114
Trade/Device Name: CUTIVA(TM) Topical Skin Adhesive (RM-1700); CUTIVA(TM) PLUS Skin Closure System (RM-1739)
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN, OMD
Dated: July 18, 2024
Received: July 18, 2024

Dear Tom Stephens:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Wilmarie Flores -S

Julie Morabito, Ph.D.
Assistant Director

DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234114

Device Name
CUTIVA™ Topical Skin Adhesive (RM1700); CUTIVA™ PLUS Skin Closure System (RM1739)

Indications for Use *(Describe)*
CUTIVA™ Topical Skin Adhesive (RM1700) is intended for topical application only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed trauma-induced lacerations. CUTIVA™ Topical Skin Adhesive (RM1700) should be used in conjunction with, but not in place of, deep dermal stitches.

The CUTIVA™ PLUS Skin Closure System (RM1739) is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. CUTIVA™ PLUS Skin Closure System (RM1739) should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during the application of the liquid adhesive.

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.

510(k) Summary

This 510(k) summary is prepared in accordance with the requirements of 21 CFR §807.92.

1. Submitter

Submitted by: Okapi Medical, LLC dba Resivant Medical
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Contact Person: Tom Stephens
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Email: tstephens@resivant.com
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Date of Summary: August 20, 2024

2. Device Name and Classification

Trade/Proprietary Name: CUTIVA™ Topical Skin Adhesive (RM1700)
Regulation Number: 21 CFR 878.4010(a)
Regulation Name: Tissue adhesive
Product Code: MPN
Classification: Class II
Panel: General and Plastic Surgery

Trade/Proprietary Name: CUTIVA™ PLUS Skin Closure System (RM1739)
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue adhesive with adjunct wound closure device intended for the topical approximation of skin
Product Code: OMD
Classification: Class II
Panel: General and Plastic Surgery

3. Predicate Device

Device Name: DERMABOND™ NX Topical Skin Adhesive (currently marketed as DERMABOND™ ADVANCED™ Topical Skin Adhesive)
510(k) File Number: K100423

Device Name: DERMABOND™ PRINEO™ Skin Closure System
510(k) File Number: K133864

4. Device Description

CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) are skin closure devices that are comprised of a 2-octyl cyanoacrylate liquid adhesive formulation. The liquid adhesive is supplied sterile within a single use dispensing applicator, which is used to deliver the adhesive to the skin. The CUTIVA™ PLUS Skin Closure System (RM1739) also incorporates a self-adhering mesh component that is applied to the wound prior to the application of the liquid adhesive to align the skin edges. The liquid adhesive is then applied to the mesh with the adhesive applicator to complete the device application.

Once applied, the liquid adhesive polymerizes to form a thin film with strong bonding and tensile properties. CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) provide a physical barrier to microbial penetration as long as the adhesive film remains intact. *In vitro* studies have been performed to demonstrate the microbial barrier properties of CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) for 72 hours after device application. No clinical studies have been performed and no clinical benefit associated with the *in vitro* microbial barrier performance of the device has been demonstrated.

5. Indications for Use

CUTIVA™ Topical Skin Adhesive (RM1700) is intended for topical application only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed trauma-induced lacerations. CUTIVA™ Topical Skin Adhesive (RM1700) should be used in conjunction with, but not in place of, deep dermal stitches.

The CUTIVA™ PLUS Skin Closure System (RM1739) is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. CUTIVA™ PLUS Skin Closure System (RM1739) should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during the application of the liquid adhesive.

6. Comparison of Technological Characteristics with Predicate

The technological characteristics of CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) are closely comparable to their respective predicate devices, DERMABOND™ NX Topical Skin Adhesive and the DERMABOND™ PRINEO™ Skin Closure System. Minor differences in technical characteristics do not raise new questions of safety and effectiveness. These technological characteristics are compared in the table on the following page.

Comparison Table of Technical Characteristics

Technical Characteristic	CUTIVA™ (RM1700)	DERMABOND™ NX	CUTIVA™ PLUS (RM1739)	DERMABOND™ PRINEO™
2-Octyl cyanoacrylate-based adhesive	Yes	Yes	Yes	Yes
Adhesive in primary packaging sterilized by dry heat to SAL 10^{-6}	Yes	Yes	Yes	Yes
Final packaged device sterilized by ethylene oxide to SAL 10^{-6}	Yes	Yes	Yes	Yes
Pen-style single use applicator	Yes	Yes	Yes	Yes
Sterile peel-open final package	Yes	Yes	Yes	Yes
Flexible tip on adhesive applicator	Yes	Yes	Yes	Yes
Polymerization initiating agent is benzalkonium chloride	Yes	Yes	Yes	Yes
Polymerizes within minutes	Yes	Yes	Yes	Yes
Forms a polymer film with strong bonding and tensile properties	Yes	Yes	Yes	Yes
Maintains skin edge approximation for natural healing	Yes	Yes	Yes	Yes
Provides a microbial barrier when the adhesive film is intact	Yes	Yes	Yes	Yes
Applicator actuation mechanism	Depress lever	Squeeze applicator	Depress lever	Twist collar
Color additive	None	D&C Violet #2	None	D&C Violet #2
Location of polymerization initiator	Adhesive applicator	Adhesive applicator	Adhesive applicator	Mesh Component

7. Performance Data

The testing plan for the CUTIVA™ Topical Skin Adhesive (RM1700) device was developed in consideration of the FDA guidance document "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin", May 30, 2008. The testing plan for the CUTIVA™ PLUS Skin Closure System (RM1739) device was developed in consideration of the FDA guidance document "Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin - Class II Special Controls Guidance Document for Industry and FDA Staff", issued November 10, 2010. Both devices were also developed according to the requirements of design control and risk analysis. Testing to establish substantial equivalence of the CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) to their respective predicate devices has been completed according to Resivant Medical procedures in compliance with the requirements of 21 CFR 820.30 – Design Control. Completed testing is listed on the following page.

Performance Testing:

Bench studies have been performed to evaluate the device properties:

- Viscosity
- Setting time
- Purity
- Moisture
- Hydrolytic degradation
- Microbial barrier

Performance studies have been performed to demonstrate substantial equivalence to the predicate devices. In all cases, the CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) devices demonstrated substantial equivalence to their respective predicates.

- Wound closure strength (ASTM F2458-05)
- Tensile strength (ASTM F2258-05)
- Lap shear strength (ASTM F2255-05)
- Heat of polymerization
- Applicator Functionality

In addition, the mesh component of the CUTIVA™ PLUS Skin Closure System (RM1739) has been tested against the performance of the mesh component of the DERMABOND™ PRINEO™ Skin Closure System predicate device. In all cases, the CUTIVA™ PLUS Skin Closure System (RM1739) mesh demonstrated substantial equivalence to the predicate mesh:

- Mesh Peel Adhesion Strength (ASTM D3330)
- Mesh Tensile Strength (ASTM D882)
- Mesh Shear Adhesion Strength (ASTM D3654)

Animal Studies:

A porcine study was conducted to compare the safety and effectiveness of CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) to their respective predicate devices in a surgically induced, full thickness, linear wound healing model over a period of 14 days. This study evaluated overall animal health, test article performance, and local tissue response to the test article. All success criteria were met for Endpoint 1 (overall animal health), Endpoint 2 (test article performance), and Endpoint 3 (local tissue response to the test article). Overall, CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) performed comparably to DERMABOND™ NX Topical Skin Adhesive and the DERMABOND™ PRINEO™ Skin Closure System, respectively.

Biocompatibility:

The biocompatibility of the CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) devices has been evaluated according to the studies recommended in ISO 10993-1:2018, “Biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process” for a device intended for prolonged contact (24 hours – 30 days) with breached skin. The results of these studies, listed below,

demonstrate that the CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) devices are safe for their intended use.

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization/Kligman Maximization (ISO 10993-10:2021)
- Irritation/Intracutaneous Reactivity (ISO 10993-10:2021)
- Material Mediated Pyrogenicity (ISO 10993-11:2017)
- Acute Systemic Injection (ISO 10993-11:2017)
- Subcutaneous Implantation (ISO 10993-6:2016)
- Subacute Systemic Toxicity (ISO 10993-11:2017)

Sterilization and Shelf-Life:

The CUTIVA™ Topical Skin Adhesive (RM1700) and the CUTIVA™ PLUS Skin Closure System (RM1739) devices are sterilized in two steps during device production. The liquid adhesive formulation is sterilized in its primary packaging by dry heat in compliance with the requirements of ISO 20857:2010. After device assembly and packaging, the finished device is sterilized by exposure to ethylene oxide gas in compliance with the requirements of ISO 11135:2014. Both sterilization processes are validated to provide a Sterility Assurance Level of 10^{-6}. The shelf life of the device has been confirmed through real-time aging studies.

8. Conclusions

The CUTIVA™ Topical Skin Adhesive (RM1700) device and its predicate device, DERMABOND™ NX Topical Skin Adhesive (K100423), have identical indications for use, function according to the same fundamental scientific technology, and are closely comparable with regard to device design and performance. Minor differences between CUTIVA™ Topical Skin Adhesive (RM1700) device and its predicate with regard to the mechanism for device actuation and the incorporation of a color additive in the predicate formulation do not raise different questions of safety or effectiveness. *In vitro* and *in vivo* testing results provided in the 510(k) submission demonstrate that the CUTIVA™ Topical Skin Adhesive (RM1700) device meets its specifications and is substantially equivalent to the DERMABOND™ NX Topical Skin Adhesive predicate.

The CUTIVA™ PLUS Skin Closure System (RM1739) device and its predicate device, DERMABOND™ PRINEO™ Skin Closure System (K133864), have identical indications for use, function according to the same fundamental scientific technology, and are closely comparable with regard to device design and performance. Minor differences between CUTIVA™ Topical Skin Adhesive (RM1700) device and its predicate with regard to the mechanism for device actuation, the incorporation of a color additive in the predicate formulation, and the location of the polymerization initiator do not raise different questions of safety or effectiveness. *In vitro* and *in vivo* testing results provided in the 510(k) submission demonstrate that the CUTIVA™ PLUS Skin Closure System (RM1739) device meets its specifications and is substantially equivalent to the DERMABOND™ PRINEO™ Skin Closure System predicate.