August 4, 2025

Okapi Medical LLC dba Resivant Medical
Stephens Tom
Sr. Director, Regulatory Affairs and Quality Assurance
526 S. Main St. Suite 124M
Akron, Ohio 44211

Re: K250950
Trade/Device Name: CUTIVA™ Topical Skin Adhesive (RM1700); CUTIVA™ PLUS Skin Closure System (RM1739)
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN, OMD
Dated: July 1, 2025
Received: July 1, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jodie Giordano -S

Jodie Giordano, Ph.D.
Acting 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)*
K250950

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 526 S. Main St. Suite 124M Akron, OH 44311 Phone: +1-234-738-4959 Web: resivant.com
Contact Person:	Tom Stephens Sr. Director, Regulatory Affairs & Quality Assurance Email: tstephens@resivant.com Phone: +1-919-616-1723
Date of Summary:	July 18, 2025

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:	CUTIVA™ Topical Skin Adhesive (RM1700)
510(k) File Number:	K234114

Device Name:	CUTIVA™ PLUS Skin Closure System (RM1739)
510(k) File Number:	K234114

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 the same as for their predicate devices. Each device references itself as predicate, as both were originally cleared in K234114. No changes to either device have been introduced in K250950, including device design, packaging, manufacturing processes, or sterilization processes.

Labeling for both devices has been modified in K250950. The package insert for the CUTIVA™ Topical Skin Adhesive (RM1700) device has been changed to remove the statement in the Warnings section that "a maximum of two (2) CUTIVA™ Adhesive devices may be used per patient application." The package insert for the CUTIVA™ PLUS Skin Closure System (RM1739) has also been changed to remove the statement in the Warnings section that "a maximum of two (2) CUTIVA™ PLUS System devices may be used per patient application." In addition, the CUTIVA™ PLUS Skin Closure System (RM1739) insert has been changed to add a statement in the Directions for Use section regarding how to manage exudate.

7. Performance Data

A biocompatibility study is included in the submission in support of the labeling changes introduced for the two devices. This study, Subacute Systemic Toxicity (Implant Method) in Rats (ISO 10993-11:2017), included the maximum dose of the test article that could be implanted in the test animals to create worst-case exposure conditions. The results of this study demonstrate that there was no evidence of systemic toxicity from the test article following subcutaneous implantation in the rat. Microscopically, the test article was classified as causing a minimal or no reaction.

8. Conclusions

The CUTIVA™ Topical Skin Adhesive (RM1700) device and its predicate (K234114) are the same device. The CUTIVA™ PLUS Skin Closure System (RM1739) device and its predicate (K234114) are also the same device. The only modifications introduced in K250950 to the devices are in their packaging inserts. The performance data provided in the 510(k) submission provide support for the labeling changes that are introduced.

Therefore, the CUTIVA™ Topical Skin Adhesive (RM1700) device and the CUTIVA™ PLUS Skin Closure System (RM1739) device are substantially equivalent to their predicate devices.