June 25, 2025

GeniPhys, Inc.
Sherry Harbin
Chief Technology Officer
7750 Zionsville Road, Suite 200
Indianapolis, Indiana 46268

Re: K250329
Trade/Device Name: GeniPhys Collymer Self-Assembling Scaffold
Regulatory Class: Unclassified
Product Code: KGN
Dated: May 23, 2025

Dear Sherry Harbin:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, PhD
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)*
K250329

Device Name
Collymer Self-Assembling Scaffold

Indications for Use *(Describe)*
Collymer Self-Assembling Scaffold is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Prepared: June 25, 2025

Submitter: GeniPhys, Inc.
7750 Zionsville Road, Suite 200
Indianapolis, IN 46268

Contact: Sherry L. Harbin, Chief Technical Officer

Proprietary Name: Collymer Self-Assembling Scaffold

Common Name: Wound Dressing with Animal-Derived Material(s)

Classification: Pre-Amendment, Unclassified

Product Code: KGN

Predicate Device: K072113 - Integra Flowable Wound Matrix, Model FWD301

Reference Devices: K030774 - Stimulen Collagen
K160136 - Flowable Wound Matrix
K222025 - G4Derm / G4Derm Plus Synthetic Wound Matrix
K182681 - AC5 Topical Gel

Device Description:
Collymer Self-Assembling Scaffold is a wound management device composed of a purified, self-assembling (scaffold-forming) collagen derived from porcine dermis. This two-part device consists of a collagen solution and a self-assembly reagent. Combining the two solutions initiates collagen self-assembly. The resulting collagen scaffold is suitable for cellularization and vascularization, providing a moist wound environment.

Indications For Use:
Collymer Self-Assembling Scaffold is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds.

Summary of Technologies/Substantial Equivalence:
Collymer Self-Assembling Scaffold is substantially equivalent to the predicate device in terms of its indications for use and technological characteristics. Table 1 provides a detailed comparison between the subject and predicate device. Minor differences between the subject device and the predicate device do not raise new types of safety and effectiveness questions. Substantial equivalence was further demonstrated by the non-clinical testing described below.

Table 1. Substantial Equivalence Comparison

	Subject Device: Collymer Self-Assembling Scaffold, K250329	Predicate Device: Integra Flowable Wound Matrix, Model FWD301, K072113	Reference: Stimulen, K030774	Reference: Flowable Wound Matrix, K160136	Reference: G4Derm / G4Derm Plus Synthetic Wound Matrix, K222025	Reference: AC5 Topical Gel, K182681	Subject Vs. Predicate Comparison
Indications for Use	Collymer Self-Assembling Scaffold is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds.	Integra Wound Matrix is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds.	Stimulen is intended for the management of wounds including full and partial thickness wounds, pressure ulcers (stage I-IV), venous stasis ulcers, diabetic ulcers, partial thickness burns, acute wounds, abrasions, traumatic wounds healing by secondary intention, donor sites and other surface wounds.	The Flowable Wound Matrix is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, 2nd degree burns, skin tears) and draining wounds.	**OTC**: May be used for superficial wounds and abrasions and minor burns. **Rx:** Under the supervision of health care professionals for the local management of partial- and full-thickness wounds including pressure, and diabetic ulcers; lower extremity ulcers including those of venous, arterial, and mixed etiology; surgical wounds; first- degree and partial- thickness burns including management of abrasions and burns associated with dermabrasions and laser resurfacing.	Under the supervision of a health care professional, AC5 Topical Gel is a topical dressing used for management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.	The subject device has the same indications for use as the predicate device.
Product Code	KGN	KGN	KGN	KGN	FRO	FRO	The subject device has the same product code as the predicate device.
Composition	Purified, acid-soluble, self-assembling type I collagen derived from porcine dermis	Granulated cross-linked bovine tendon collagen and glycosaminogly can	Bovine based, purified, soluble modified collagen	Particulate porcine small intestinal submucosa and fructose	Aqueous solution of synthetic peptides	Synthetic self-assembling peptides and sterile water for injection	The subject device, the predicate device, and the reference devices Stimulen (K030774) and Flowable Wound Matrix (K160136) use animal-based collagen sources. Collagen characterization demonstrated that there are no new safety or effectiveness questions.
Gel or Scaffold Form	Yes	Yes	Yes	Yes	Yes	Yes	The subject device, the predicate device, and all reference devices form a gel/scaffold material.
Form and Presentation	Acidified collagen solution that when mixed with a phosphate-based buffer and applied topically using a dual syringe/luer	Crosslinked collagen and glycosamino-glycan particulate rehydrated to a gel-like consistency	Collagen powder that when applied topically dissolves in wound exudate and forms a collagen gel;	Particulate small intestinal submucosa and fructose rehydrated to a gel-like consistency using saline in a	Aqueous solution of synthetic peptides (shear-thinning) that when applied topically using a syringe/applicat	Lyophilized self-assembling synthetic peptide that is reconstituted in water to create an acidic peptide	The subject device, the predicate device, and all reference devices are applied topically and result in a gel or scaffold form.

	Subject Device: Collymer Self-Assembling Scaffold, K250329	Predicate Device: Integra Flowable Wound Matrix, Model FWD301, K072113	Reference: Stimulen, K030774	Reference: Flowable Wound Matrix, K160136	Reference: G4Derm / G4Derm Plus Synthetic Wound Matrix, K222025	Reference: AC5 Topical Gel, K182681	Subject Vs. Predicate Comparison
	connector system forms a collagen scaffold	using saline in a dual syringe/luer connector system and then applied topically	other product formats represent a flowable gel or a pre-formed sheet	dual syringe/luer connector system and then applied topically	or system forms a gel	solution; when applied topically using a syringe/ applicator system, the peptide solution interacts with endogenous ions in wounds and self-assembles to form a scaffold	
Biocompat-ible	Yes	Yes	Yes	Yes	Yes	Yes	The subject device, the predicate device, and all reference devices are all biocompatible.
Sterile Formulation	Yes	Yes	Yes	Yes	Yes	Yes	The subject device, the predicate device, and all reference devices are all supplied sterile.
Single Use	Yes	Yes	Yes	Yes	Yes	Yes	The subject device, the predicate device, and all reference devices are all single use.

Non-Clinical Testing:

Collymer Self-Assembling Scaffold underwent non-clinical testing and analyses to support a determination of substantial equivalence to the predicate device. The following were completed:

Biocompatibility Assessments

The biocompatibility assessment of the Collymer Self-Assembling Scaffold was conducted in accordance with ISO 10993-1 and FDA's guidance on the use of ISO 10993-1. The testing included chemical characterization, applicable ISO 10993-1 biocompatibility endpoints, and a toxicological risk assessment. All results met the acceptance criteria. No evidence of adverse biological responses was observed, and the device is deemed safe and suitable for its intended use.

Viral Inactivation

A viral inactivation study was completed to confirm compliance to ISO 22442-3 and FDA Guidance: "Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)." The study results demonstrated that the manufacturing process steps evaluated are effective in achieving viral inactivation, ensuring the safety of the device under the conditions tested.

Sterility Assessment

A sterility assessment was conducted in accordance with FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," January 2024 and FDA Guidance, "Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice," September 2004. The assessment concluded that the process methods and controls consistently produce a sterile final Collymer Self-Assembling Scaffold device.

Shipping Study

A shipping study was completed in accordance with ASTM D4169. The results demonstrated that the packaging design is appropriate for its intended use.

Stability Evaluation

A stability (real-time aging) study was completed on Collymer Self-Assembling Scaffold to ensure the device materials and associated primary packaging remain stable for at least 6 months when stored under refrigerated conditions (5±3ºC). The product was evaluated for chemical, physical, and self-assembling properties, container closure integrity, sterility, and chemical and elemental impurities. The acceptance criteria were met, demonstrating stability of the device for at least 6 months at 5±3ºC.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of Collymer Self-Assembling Scaffold to the predicate device.

Conclusion:

A comparison of the subject and predicate device, including comparison of the intended use and technological characteristics has demonstrated that the subject device is as safe and effective as the predicate device. Thus, the subject device is substantially equivalent to the predicate device.