Biogennix, LLC
% Elaine Duncan
President
Paladin Medical, Inc.
PO Box 560
Stillwater, Minnesota 55082

March 30, 2020

Re: K193487
Trade/Device Name: Agilon Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: March 3, 2020
Received: March 4, 2020

Dear Ms. Duncan:

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,

Jesse Muir, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193487

Device Name
Agilon Strip

Indications for Use *(Describe)*
Agilon Strip is indicated for use in voids or gaps of the skeletal system, i.e., the extremities, pelvis, and posterolateral spine, that are not intrinsic to the stability of the bony structure. These osseous defects may be created surgically or from traumatic injury. Agilon Strip may be used alone in the extremities and pelvis but must be mixed with autograft when used in the posterolateral spine. Agilon Strip resorbs and is replaced with bone during the healing process.

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.

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510(K) SUMMARY

I. SUBMITTER

Submitted on behalf of:

Company Name:	BIOGENNIX, LLC
Address:	1641 McGaw Ave. Irvine, CA 92614
Telephone:	949-253-0094
Fax:	949-266-5800
by:	Elaine Duncan, M.S.M.E., RAC President, Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082
Telephone:	715-549-6035
Fax:	715-549-5380
Contact Person:	Elaine Duncan
Date Prepared:	December 13, 2019

II. SUBJECT DEVICE

Trade Name:	Agilon Strip
Common Name(s):	Bone void filler, Bone graft substitute, Bone graft extender
Regulation Number:	21 CFR 888.3045
Regulation Name:	Resorbable calcium salt bone void-filler device
Product Code:	MQV
Regulatory Class:	II

III. PREDICATE DEVICE

The contents of this submission have demonstrated that Agilon Strip is substantially equivalent to its primary predicate Morpheus (K142828) when used as a bone graft substitute in the extremities and pelvis, and as a bone graft extender in the posterolateral spine.

IV. DEVICE DESCRIPTION

Agilon Strip is a flexible, resorbable, wicking, osteoconductive bone graft substitute composed of 1-2mm osteoSPAN granules bound by type I collagen fibers to facilitate shaping and containment of the implant.

510(k) Summary-Continued

The osteoSPAN granules in Agilon Strip are approximately 65% porous, biphasic calcium salts with interconnected pores having a nominal cross-section of 500 microns. The primary composition of each granule is calcium carbonate, with a thin layer of calcium phosphate throughout its entire porosity.

V. INDICATIONS FOR USE

Agilon Strip is indicated for use in voids or gaps of the skeletal system, i.e., the extremities, pelvis, and posterolateral spine, that are not intrinsic to the stability of the bony structure. These osseous defects may be created surgically or from traumatic injury. Agilon Strip may be used alone in the extremities or pelvis but must be mixed with autograft when used in the posterolateral spine. Agilon Strip resorbs and is replaced with bone during the healing process.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Product	510(k) Number	Granules Composition	Polymer Binder	Collagen	Osteo-conductive
Morpheus	K132377 K142828	Calcium Carbonate/ Calcium Phosphate composite	Yes	No	Yes
Agilon Strip	K193487	Identical	No	Yes	Yes

The function, intended use and technological characteristics of the subject device are substantially equivalent to the predicate device cleared under 510(k) premarket notification K142828.

VII. PERFORMANCE DATA

Biogennix followed the “Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device: Guidance for Industry and FDA, June 2, 2003, as well as the company’s design controls and risk analysis procedures to ensure that Agilon Strip is safe and effective for use.

Bench testing of Agilon Strip was performed to verify that the addition of the type 1 collagen does not affect the granule chemistry, crystallinity, porosity, pore diameter, and pore interconnectivity. Sterilization validation and shelf-life aging studies demonstrate the suitability of the packaging system.

A full evaluation of the biocompatibility of Agilon Strip was conducted in accordance with “*Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.” As a tissue/bone

510(k) Summary-Continued

permanent implant device, Agilon Strip satisfied a battery of tests assessing the following biological effects:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Bacterial Endotoxins
- Subchronic toxicity
- Genotoxicity
- Implantation

In vivo testing of Agilon Strip was conducted using a validated, critically sized defect model. Device performance was assessed at multiple time points against the primary predicate and negative controls using histology, histomorphometry, x-ray, and micro-CT analyses. The critical nature of the model was confirmed by the negative controls. No adverse reactions were noted at the implant site or in distant organs; new bone formation, bone remodeling, and implant resorption for the test materials were confirmed with time.

Agilon Strip was also validated in a clinically relevant, single-level posterolateral spinal fusion model. Device performance was evaluated at multiple time points against the primary predicate and positive control using mechanical, histology, histomorphometry, x-ray, and micro-CT analyses. Fusion rates were the same between all treatment groups at each time point and consistent with published literature. No adverse events or device-related failures were noted at the implantation site or distant organs for any implant group. No abnormal inflammation, redness, swelling, or discoloration was noted at any time point. New bone formation on the host transverse bone processes, as well as evidence of resorption and remodeling of the graft materials, were confirmed with time.

Based on the endpoints and results of these studies, Agilon Strip was concluded to be substantially equivalent to the primary predicate osteoSPAN Morpheus.

VIII. CONCLUSIONS

The non-clinical data presented in this submission demonstrates that Agilon Strip is substantially equivalent to the predicate device osteoSPAN Morpheus.