February 13, 2020

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

Re: K193168
Trade/Device Name: Agilon Moldable
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: November 12, 2019
Received: November 18, 2019

Dear Elaine 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,

Laura C. Rose, PhD
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)*
K193168

Device Name
Agilon Moldable

Indications for Use *(Describe)*
Agilon Moldable 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. The product may be used alone in the extremities and pelvis but must be mixed with autograft when used in the posterolateral spine. Agilon Moldable 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.

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510(K) SUMMARY

K193168

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:	November 12, 2019

SUBJECT DEVICE

Trade Name:	Agilon Moldable
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

PREDICATE DEVICE

The contents of this submission have demonstrated that Agilon Moldable is substantially equivalent to Morpheus (K142828) when used as a bone graft extender in the posterolateral spine.

Morpheus-C, cleared to market as a bone graft substitute (K190371) and now marketed as Agilon Moldable, was used as a reference device.

DEVICE DESCRIPTION

Agilon Moldable collagen enhanced bone graft substitute is a moldable, resorbable osteoconductive bone void filler composed of 1-2mm osteoSPAN granules suspended in a biocompatible organic binder to facilitate implant mixing, shaping, and containment. The osteoSPAN granules in the product 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. The organic binder is a combination of a biocompatible polymer and type I collagen fibers to provide enhanced intraoperative handling. The polymer is rapidly absorbed in-situ, leaving behind osteoSPAN granules and collagen fibers as an osteoconductive scaffold.

INDICATIONS FOR USE

Agilon Moldable 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. The product may be used alone in the extremities and pelvis but must be mixed with autograft when used in the posterolateral spine. Agilon Moldable resorbs and is replaced with bone during the healing process.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE AND REFERENCE DEVICES

Apart from the type I collagen in the subject device, the function, intended use, and technological characteristics of the subject and predicate devices are identical.

Product	510(k) Number	Granules Composition	Polymer Binder	Collagen	Osteo-conductive
Morpheus (Predicate Device)	K142828	Calcium Carbonate/ Calcium Phosphate composite	Yes	No	Yes
Agilon Moldable (Reference Device)	K190371	Identical	Identical	Yes	Yes

PERFORMANCE DATA

Agilon Moldable, the subject device, is IDENTICAL to reference device cleared under K190371. Biogennix followed the “Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device: Guidance for Industry and FDA, June 2, 2003”, and the company’s design controls and risk analysis procedures to ensure the product is safe and effective for use. Biocompatibility testing and other performance characterization prescribed in “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation within a risk management process’” was provided in submission K190371.

This submission includes *in vivo* testing results of the product in a validated, clinically relevant, single-level posterolateral spinal fusion model. Device performance was compared at multiple time points against the predicate and positive control (autograft) 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 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.

CONCLUSIONS

The pre-clinical data presented in this submission demonstrate that Agilon Moldable is substantially equivalent to Morpheus when used as an autograft extender in the posterolateral spine.