September 30, 2025

Wright Medical Technology, Inc. (Stryker Corporation)
Alayne Melancon
Manager, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

Re: K252085
Trade/Device Name: Allomatrix (Allomatrix Injectable Putty; Allomatrix C; Allomatrix DR; Allomatrix Custom)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: July 2, 2025
Received: July 2, 2025

Dear Alayne Melancon:

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.09.30 14:29:07 -04'00'

Jesse Muir, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252085

Please provide the device trade name(s).

Allomatrix (Allomatrix Injectable Putty, Allomatrix C, Allomatrix DR, Allomatrix Custom)

Please provide your Indications for Use below.

Allomatrix® Injectable Putty, Allomatrix C, and Allomatrix® DR products are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Allomatrix® products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

AlloMatrix® Custom Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of bony structure. AlloMatrix® Custom Putty is intended to be gently packed into bony voids or gaps of the skeletal system as a bone graft extender (spine), and as a bone void filler in the extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

stryker

510(K) SUMMARY

ALLOMATRIX® Injectable Putty, ALLOMATRIX® C, ALLOMATRIX® Custom and ALLOMATRIX® DR

(a)(1).	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	July 2, 2025
	Contact Person:	Alayne Melancon Manager, Regulatory Affairs
	Secondary Contact:	Leslie Fitch Director, Regulatory Affairs
(a)(2).	**Proprietary Name:**	Allomatrix®
	Common Name:	Bone Void Filler
	Classification Name and Reference:	21 CFR 888.3045 – Class II
	Device Product Code, Device Panel:	MQV, MBP
(a)(3).	**Primary Predicate Device(s):**	Allomatrix® Putty (K041168), Allomatrix® C (K040980), Allomatrix® DR (K040980), Allomatrix® Custom (K061939)

(a)(4). Device Description

The Allomatrix® family of bone void fillers are comprised of demineralized bone matrix (DBM), a range of cancellous bone matrix (CBM) granules, and a binder of surgical-grade calcium sulfate and carboxymethylcellulose (CMC). Allomatrix® is available in four formulations and various volumes to accommodate surgeon needs. After mixing, the resultant putty can then be handled and placed in the appropriate bone voids.

(a)(5). Indications for Use

Allomatrix® Injectable Putty, Allomatrix C, and Allomatrix® DR products are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Allomatrix® products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

AlloMatrix® Custom Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of bony structure. AlloMatrix® Custom Putty is intended to be gently packed into bony voids or gaps of the skeletal system as a bone graft extender (spine), and as a

bone void filler in the extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

(a)(6). Technological Characteristics Comparison

The subject Allomatrix® devices are substantially equivalent to the predicate devices in material and design.

There is no change in the fundamental scientific technology shared by both the subject and predicate devices. The subject and predicate implants have identical materials, design features, instrumentation, and performance characteristics. Non-clinical performance testing has confirmed substantial equivalence of the subject device, demonstrating that the change in supplier for demineralized and cancellous bone matrix do not raise new questions of safety or effectiveness.

(b)(1). Substantial Equivalence - Non-Clinical Evidence

Non-clinical performance testing (handleability, osteoinductivity, viral inactivation, and material characterization) was performed to demonstrate substantial equivalence to the predicate device.

(b)(2). Substantial Equivalence - Clinical Evidence

N/A - Clinical testing was not necessary for the determination of substantial equivalence.

(b)(3). Substantial Equivalence - Conclusions

The subject device and predicate device share identical intended use, general design features, and basic fundamental scientific technology. The differences between the subject device and predicate device do not raise any new questions of safety or effectiveness. From the evidence submitted in this Traditional 510(k), the subject device can be expected to perform at least as well as the predicate device and are substantially equivalent.