July 29, 2025

Forcyte Medical LLC
℅ Cheryl Wagoner
Consultant
Wagoner Consulting LLC
5215 Crosswinds Drive
Wilmington, North Carolina 28409

Re: K243407
Trade/Device Name: Forcyte Autograft Harvest Kit
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 29, 2025
Received: May 29, 2025

Dear Cheryl Wagoner:

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: 2025.07.29 09:48:29 -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

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.

Submission Number *(if known)*

K243407

Device Name

Forcyte Autograft Harvest Kit

Indications for Use *(Describe)*

FORCYTE Autograft Harvest Kit is intended to harvest cancellous bone and bone marrow for combination with commercially available allograft or bone void fillers for filling bony voids or gaps that are not intrinsic to the stability of the bony structure.

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) #: K243407

510(k) Summary

Prepared on: 2025-07-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Forcyte Medical LLC
Applicant Address	2275 Northwest Parkway SE, Suite 160 Marietta GA 30067 United States
Applicant Contact Telephone	612-860-1232
Applicant Contact	Mr. Robert Assell
Applicant Contact Email	rassell@forcytemed.com
Correspondent Name	Wagoner Consulting LLC
Correspondent Address	5215 Crosswinds Drive Wilmington NC 28409 United States
Correspondent Contact Telephone	910-386-9019
Correspondent Contact	Ms. Cheryl Wagoner
Correspondent Contact Email	cheryl@wagonerconsultingllc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Forcyte Autograft Harvest Kit
Common Name	Gastroenterology-urology biopsy instrument
Classification Name	Instrument, Biopsy
Regulation Number	876.1075
Product Code(s)	KNW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210631	Avitus Precision Autograft Delivery	KNW

Device Description Summary

21 CFR 807.92(a)(4)

The Subject device is a kit comprised of a bone and marrow harvesting needle, collection jar, suction tubing, drill-tip guide pin, and bone void filler hydration chamber. The FORCYTE system harvests autologous bone and marrow for use as a bone void filler.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

FORCYTE Autograft Harvest Kit is intended to harvest cancellous bone and bone marrow for combination with commercially available allograft or bone void fillers for filling bony voids or gaps that are not intrinsic to the stability of the bony structure.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Subject device and its predicate have similar technology. The intended use are the same with some wording differences.

Technological Comparison 21 CFR 807.92(a)(6)

The Subject and predicate devices have similar technological characteristics as manual autograft harvesting instrumentation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

There are not specific test standards that are applicable for performance testing of this device. However, bench testing including simulated use testing, tensile, compression, torque, flexural, and vacuum testing were conducted. No clinical evaluations were conducted. Sterilization/shelf life testing were conducted. All testing had satisfactory results.

The biocompatibility, sterilization, and bench testing all indicate that the Subject device is safe, effective and performs as intended and as well as its predicate.