August 6, 2025

Tecres S.p.A.
% Michael Coladonato
Associate Director, Regulatory Affairs
MCRA
803 7th Street NW
Washington, District of Columbia 20001

Re: K252326
Trade/Device Name: InterSpace GV Hip Spacer
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWL, KWY, MBB
Dated: July 25, 2025
Received: July 25, 2025

Dear Mr. Coladonato:

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: 2025.08.06 09:07:35 -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.	K252236

Please provide the device trade name(s).

InterSpace GV Hip Spacer

Please provide your Indications for Use below.

The InterSpace GV Hip Spacer is indicated for temporary use (maximum 180 days) as a total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin and vancomycin are the most appropriate antibiotics based on the susceptibility pattern of the infecting micro-organism(s).

The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The InterSpace GV Hip Spacer is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.).

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)

510(k) Summary

Submitter: Tecres, S.p.A
Via Andrea Doria, 6
Sommacampagna, Italy 37066

Official Correspondent: Michael Coladonato
Associate Director, Regulatory Affairs
MCRA, LLC
803 7th Street, NW, 4th Floor
Washington, DC 20001
Phone: (202) 552-5800
mcoladonato@mcra.com

Date Prepared: July 25, 2025

Trade Name: InterSpace GV Hip Spacer

Common Name: prosthesis, hip, hemi-, femoral, metal

Classification: Class II
21 CFR 888.3360, Hip Joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

Product Code: KWL, KWY, MBB

Predicate Device: InterSpace G (K031841)

Reference Device: REMEDY Plus Hip Spacer, OsteoRemedies, LLC (K172906)

Device Description:

The InterSpace GV Hip Spacer is manufactured from PMMA with gentamicin and vancomycin and includes a stainless-steel core as well as a tapered wedge design. The InterSpace GV Hip Spacer is single-use, disposable, and provided sterile. The InterSpace GV Hip Spacer is inserted into the femoral medullary canal and acetabular cavity following the removal of the existing femoral and acetabular implants and debridement as part of a two-stage procedure due to a septic process. The device is protected from bacterial colonization due to the presence of gentamicin and vancomycin.

Indications for Use:

The InterSpace GV Hip Spacer is indicated for temporary use (maximum 180 days) as a total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin and vancomycin are the most

appropriate antibiotics based on the susceptibility pattern of the infecting micro-organism(s).

The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The InterSpace GV Hip Spacer is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.).

Substantial Equivalence:

The subject InterSpace GV Hip Spacer is substantially equivalent to the InterSpace G (K031841), and the REMEDY SPECTRUM GV Hip (K172906) with respect to intended use, materials, and function. The minor geometric change (i.e., tapered wedge stem) has been assessed via mechanical testing to demonstrate substantial equivalence compared to the predicate. The information summarized in the Design Control Activities Summary demonstrates that the subject InterSpace GV Hip Spacer met the pre-determined acceptance criteria for the verification activities.

Performance Testing of Subject InterSpace GV Hip Spacer:

The following tests have been performed on InterSpace GV Hip Spacer.

- Mechanical Testing
- Analysis of Antibiotic Content
- Biocompatibility Assessment
- Sterilization Validation
- Shelf-Life Validation
- Packaging Validation