Companion Spine France
℅ Lucas Tatem
Manager, Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K253118
Trade/Device Name: Companion Spine DIAM™ Instrumentation
Regulation Number: 21 CFR 888.4520
Regulation Name: Manual Instruments Designed For Use With Non-Fusion Spinous Process Spacer Devices
Regulatory Class: Class II
Product Code: QLR, KCT
Dated: September 24, 2025
Received: September 24, 2025

Dear Lucas Tatem:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.	K253118

Please provide the device trade name(s).

Companion Spine DIAM™ Instrumentation

Please provide your Indications for Use below.

The Companion Spine DIAM™ Instrumentation is indicated for the insertion and positioning of the Companion Spine DIAM™ Spinal Stabilization System devices, or if required, removal of the implantable device.

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

Device Trade Name: Companion Spine DIAM™ Instrumentation

Manufacturer:
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Prepared by:
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Date Prepared: September 24, 2025

Classifications: Manual Instruments Designed For Use With Non-Fusion Spinous Process Spacer Devices, and Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

Regulatory Class: II

Product Codes: QLR, KCT (888.4520, 880.6850)

Primary Predicate: coflex Interlaminar Technologies Instrumentation (Q200824)

Indications For Use:

The Companion Spine DIAM™ Instrumentation is indicated for the insertion and positioning of the Companion Spine DIAM™ Spinal Stabilization System devices, or if required, removal of the implantable device.

Device Description:

The Companion Spine DIAM™ Instrumentation are non-implant devices that consist of device-specific instruments for use in implantation of Companion Spine DIAM™ Spinal Stabilization System devices. These instruments are manual and non-powered surgical tools with implant specific geometry that are intended to manipulate tissue or implant materials for the positioning, alignment, placement, or removal of spinous process spacer devices for non-fusion use.

Predicate Device:

Companion Spine submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, DIAM™ Instrumentation is substantially equivalent in indications, design principles, and performance to the following predicate device, which have been determined by FDA to be Class II.

Primary Predicate: coflex Interlaminar Technology Instrumentation (RTI Surgical, Inc., Q200824)

Performance Testing Summary:

The subject instruments were validated for their intended use in a cadaver model per the surgical technique. The design outputs were found to meet the customer needs, and there were no outstanding dispositions of features. The Crimper was evaluated to verify that over-compression and under-compression do not occur on the ligament. The mean peak load of the static tensile test utilizing all crimper and crimp conditions were found to exceed the mean failure load of a lumbar spinous process. Additionally, testing was performed to verify that the wings of all sizes of the DIAM™ Spinal Stabilization System implant can be folded and handled by the two types of inserters, in accordance with the surgical technique, without damaging the implant. Both inserters were demonstrated to perform as intended without damaging the integrity of the implant.

Substantial Equivalence:

The Companion Spine DIAM™ Instrumentation is substantially equivalent to the predicate coflex Interlaminar Technology Instrumentation in regard to intended use, operating principles and technological characteristics. Both the subject and predicate systems include manual surgical instruments and sterilization trays specifically designed for use with a non-fusion spinous process spacer device.

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.