January 15, 2026

BAAT Medical Products B.V.
Jasper Springer
Regulatory Affairs Officer
F. Hazemeijerstraat 800
Building A04
Hengelo, Overijssel 7555 RJ
Netherlands

Re: K251961
Trade/Device Name: SDS Growing Rod
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: PGM
Dated: December 15, 2025
Received: December 16, 2025

Dear Jasper Springer:

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

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.

510(k) Number *(if known)*
K251961

Device Name
SDS™ Growing Rod

Indications for Use *(Describe)*

The SDS Growing Rod is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome.

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.

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510(k) Summary

1. Applicant/Submitter

Submitter Name: BAAT Medical Products B.V.
Submitter Address: F. Hazemeijerstraat 800 - Building A04
7555 RJ Hengelo
The Netherlands

Phone Number: +31-(0)88-5656600

Contact person: Jasper Springer

Date Prepared: 26th of June, 2025

2. Device

Device Trade name: SDS Growing Rod

Common Name: Not Applicable

Classification: 888.3070 - Thoracolumbosacral pedicle screw system

Product Code/s: PGM – Growing Rod System

Review Panel: Orthopedic devices

3. Predicate Device

SHILLA™ Growth Guidance System (K140750)

4. Description of the Device

The SDS Growing Rod is an implant designed to correct and actively lengthen the spine in children with early onset spinal deformities while allowing growth, without the need for re-operations or other interventions. This is achieved by a spinal construct with one or two springs and sliding bearings. The spring provides a distraction force to correct the spinal curve while the sliding bearing is designed to enable growth by allowing displacement of one rod with respect to the other rod.

The SDS Growing Rod is available with 5.5 mm rods. Two configurations of the SDS Growing Rod are possible: hybrid and bilateral. The SDS Growing Rod is delivered sterile and is for single use only. The intended lifetime of the SDS Growing Rod while allowing growth is up to 5 years. The SDS Growing Rod is removed or locked after the treatment is completed.

The SDS Growing Rod is composed out of the following components:

- Titanium alloy springs with UHMWPE bushings
- Titanium alloy Axial Sliding Bearing with UHMWPE bearings

- Titanium alloy Polyaxial Sliding Bearing with UHMWPE bearings
- Titanium alloy buttress
- CoCr rods
- Titanium alloy C-Clamp

The SDS Growing Rod is used in combination with:

- Dedicated instrument set
  - Spring Compressor
  - Spring Locker
  - Torque Limiting Handle 9Nm
  - C-Clamp Forceps
  - SDS Tray
- Pedicle screws for 5.5 mm rods. The SDS Growing Rod is compatible with pedicle screws from the RESPONSE™ 5.5/6.0 mm System (Orthopediatrics) and their dedicated instrumentation for screw placement. Other components of the RESPONSE™ system, such as connectors, hooks, or ancillary fixation elements, may be used within the same spinal construct as clinically indicated. However, these components should not impede the sliding function of the growing rod or integrated spring mechanism.

5. Indication for Use Statement

The SDS Growing Rod is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome.

6. Summary of Technological Characteristics of the Device Compared to the Predicate device

The technological characteristics of the subject device are similar to those of the predicate device, although they are not identical. Both devices consist of spinal rods and associated fixation components intended to maintain spinal correction while allowing controlled spinal growth over time, and both systems are designed to accommodate longitudinal adjustment during the growth period.

The primary differences between the subject and predicate devices relate to the specific configuration of components and the mechanism by which controlled motion and actuation are achieved. The subject device employs alternative interconnections and actuation mechanisms compared to the predicate device. These differences do not raise different questions of safety or effectiveness, as they are limited to the manner of implementation rather than the fundamental technological function.

7. Summary of Performance Data, Clinical Data, and Design Controls

The SDS Growing Rod has undergone comprehensive non-clinical performance testing to verify mechanical integrity and functional equivalence to the predicate device.

Testing was performed in accordance with FDA-recognized consensus standards, including ASTM F1717 (Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model), and ASTM F1798 (Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms). Wear was evaluated via a setup based on ASTM F1717 and a test procedure derived from applicable wear standards (ASTM F2624).

Biocompatibility was addressed in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*. A risk-based biological evaluation was performed considering the materials, manufacturing processes, and clinical use of the device. Based on this evaluation and supporting evidence, the device is considered biocompatible and safe for its intended use.

Retrospective clinical data on the subject device were provided in support of this submission. The clinical outcomes demonstrated the SDS Growing Rod to have a substantially equivalent safety and effectiveness profile compared to predicates when treating the same patient population. Clinical data analyses demonstrated safe use with adequate mitigation of risks associated with the metallic components of the device, including potential tissue ingrowth/encapsulation, local tissue reactions from wear or corrosion byproducts, and irritation from spring or sliding elements.

The results support the conclusion that the SDS Growing Rod performs at least as safely and effectively as predicate pedicle screw-based growing rod systems under similar conditions of use.

8. Conclusion of Substantial Equivalence

The SDS Growing Rod has the same intended use, similar indications for use, similar technology, comparable principles of operation, same range of size parameters, and similar materials as the identified predicate device.

The differences encountered do not negatively impact the overall safety and effectiveness of the SDS Growing Rod. Therefore, it can be concluded that the SDS Growing Rod is a safe and effective device and is substantially equivalent to the identified predicate system.