July 29, 2022

Medos International Sárl
c/o Kirsten Lehmuller
DePuy Spine, *a Johnson & Johnson Company*
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K141509
Trade/Device Name: ISOLA® and EXPEDIUM® Growing Spine Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Kirsten Lehmuller:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 22, 2014. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2014

Medos International Sárl
% Ms. Kirsten Lehmuller
DePuy Spine, *a Johnson & Johnson Company*
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K141509
Trade/Device Name: ISOLA® and EXPEDIUM® Growing Spine Systems
Regulatory Class: Unclassified
Product Code: PGM
Dated: June 5, 2014
Received: June 10, 2014

Dear Ms. Lehmuller:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141509

Device Name
ISOLA® and EXPEDIUM® Growing Spine Systems

Indications for Use *(Describe)*
The ISOLA® Growing Spine System is indicated for patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The ISOLA® Growing Spine System may be used with any cleared traditional ISOLA® Spine System 3/16 inch rod constructs.

The EXPEDIUM® Growing Spine System is indicated for patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The EXPEDIUM® Growing Spine System may be used with any cleared traditional 4.5 and 5.5 EXPEDIUM® Spine Systems. The EXPEDIUM® Growing Spine System is not intended to be used with 4.0mm diameter screws.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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) SUMMARY

A. Submitter Information

Medos International Sárl
Chemin-Blanc 38
2400 Le Locle, Switzerland

Contact Person:	Kirsten Lehmuller
Address:	325 Paramount Drive Raynham, MA 02767
Telephone number:	508-828-3291
Fax number:	508-828-3797
Email:	klehmull@its.jnj.com

B. Date Prepared June 5, 2014

C. Device Name

Trade/Proprietary Name:	ISOLA® and EXPEDIUM® Growing Spine Systems
Common/Usual Name:	Growing Rod System
Classification Name:	Unclassified
Product Code:	PGM

D. Predicate Device Name

Trade name:	Medtronic CD Horizon® Growth Rod Conversion Set (K133904) EXPEDIUM Spine System (K111136) ISOLA Spine System (K980485) Harrington Spinal Rod System (Pre-Amendment)

E. Device Description

The ISOLA and EXPEDIUM Growing Spine Systems consist of an assortment of connectors designed to convert a traditional fusion construct into a non-fusion growth enabling construct that can be surgically lengthened on a periodic basis as the patient

grows. The ISOLA and EXPEDIUM Growing Spine Systems' components are manufactured from titanium alloy and stainless steel and are designed to interact with constructs consisting of rods ranging in diameter from 4.5 to 5.5mm, hooks, screws, offset connectors, and cross connectors. The ISOLA and EXPEDIUM Growing Spine Systems are intended for use only with ISOLA (3/16 inch rod diameter) and EXPEDIUM Spinal Systems (4.5 and 5.5mm rod diameter) fusion constructs for cleared pediatric use.

F. Intended Use

The ISOLA Growing Spine System is indicated for patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The ISOLA Growing Spine System may be used with any cleared traditional ISOLA Spine System 3/16 inch rod constructs.

The EXPEDIUM Growing Spine System is indicated for patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The EXPEDIUM Growing Spine System may be used with any cleared traditional 4.5 and 5.5 EXPEDIUM Spine Systems. The EXPEDIUM Growing Spine System is not intended to be used with 4.0mm diameter screws.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The subject ISOLA and EXPEDIUM Growing Spine Systems have the same fundamental technology and intended use as the predicate Harrington Spinal Rod System (pre-amendment) and CD HORIZON® Growth Rod Conversion Set (K133904, SE 02/25/2014) for the treatments of spinal deformities in a non-fusion manner. Additionally, the subject extended tandem connectors are substantially equivalent to tandem connectors previously cleared in the ISOLA Spine System (K922504, K980485). The subject devices are similar in materials, manufacturing, and sterilization as the previously cleared ISOLA and EXPEDIUM Spine Systems.

G. Materials

The ISOLA and EXPEDIUM Growing Spine Systems are manufactured from ASTM F-138 implant grade stainless steel and ASTM F-136 implant grade titanium alloy.

H. Performance Data

Performance data per ASTM F 1717 (static and dynamic compression bending and static torsion) were submitted to characterize the subject ISOLA and EXPEDIUM Growing Spine Systems components addressed in this notification.

I. Conclusion

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the proposed device is substantially equivalent to the predicate devices.