April 2, 2025

Orthocell Ltd.
℅ Kristin Zielinski Duggan
Partner, Hogan Lovells US LLP
Columbia Square, 555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K243889
Trade/Device Name: Remplir (ON-152, 15 x 20 mm); Remplir (ON-203, 20 x 30 mm); Remplir (ON-304, 30 x 40 mm); Remplir (ON-405, 40 x 50 mm)
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: December 18, 2024
Received: December 18, 2024

Dear Kristin Zielinski Duggan:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.04.02 15:45:27 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
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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)*

K243889

Device Name

Remplir (ON-152, 15 x 20 mm);
Remplir (ON-203, 20 x 30 mm);
Remplir (ON-304, 30 x 40 mm);
Remplir (ON-405, 40 x 50 mm)

Indications for Use *(Describe)*

Remplir is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

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

Remplir™

SUBMITTER

Name	Orthocell Ltd
Address	Building 191, Murdoch University South Street, Murdoch WA 6150 AUSTRALIA
Contact Person	Kelly Hunter
Phone	+ 61 8 9360 6268
Date	April 2, 2025

DEVICE

Trade Name:	Remplir™
Common Name	Nerve Wrap
Classification Name:	Nerve Cuff (21 CFR 882.5275)
Regulatory Class:	Class II
Product Code:	JXI

PREDICATE DEVICE

Remplir™ is substantially equivalent in function and intended use to following predicate device:

Trade Name:	NeuraWrap™
Classification Name:	K041620

DEVICE DESCRIPTION

Remplir™ is a sterile, implantable, biocompatible, resorbable, collagen membrane intended for use in the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue. Remplir™ is a single-ply sheet of porcine-derived, non-crosslinked collagen. It presents as a soft and pliable, white to off-white membrane with distinct smooth and rough surfaces.

The primary aim of surgical repair is to re-establish nerve continuity so that regenerating axons are guided into the distal nerve stump with minimal loss of nerve fibres at the repair site. Remplir™ is designed to protect the injured nerve. The device can be cut to the desired size and wrapped around the injured nerve in either its wet or dry form. It is wrapped around the site of nerve repair, intended to provide a favourable environment for nerve regeneration and prevent ingrowth of connective tissue.

Remplir™ is supplied as a single device in a double PETG/Tyvek blister pack in a labelled cardboard box. Remplir™ is available in 4 size variants for the convenience of clinicians (15 mm x 20 mm, 20 mm x 30 mm, 30 mm x 40 mm, 40 mm x 50 mm.). All size variants are identical in composition and function.

INDICATIONS FOR USE

Remplir™ is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device (Remplir™) is substantially equivalent in function, intended use/indications for use and technological characteristics of the predicate device (NeuraWrap™). The table below summarizes the comparison between the predicate device and Remplir™.

Device Comparison Table: Remplir™ and NeuraWrap™		
Device	**Remplir™** (Subject device)	**NeuraWrap™** (Predicate, K041620)
Indications for use	Remplir™ is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.	NeuraWrap™ is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.
Configuration / Presentation	Presents as a flexible, dry, white sheet. Rollable sheet	Presents as a flexible, dry, white sheet Hollow Tube
Composition	Type 1 collagen, porcine	Type 1 collagen, bovine
Technological characteristics	Resorbable Suturable Absorbent Retains mechanical strength when wet	Resorbable Suturable Absorbent Retains mechanical strength when wet
Sterile/Single Use	Sterile; single use	Sterile; single use
Packaging	Double PETG trays with Tyvek® seals	Double PETG trays with Tyvek® seals
Sterilization	Gamma Irradiation	Ethylene Oxide (EO)

PERFORMANCE DATA

The following performance data was performed on the Remplir™ nerve wrap device.

Purpose of Test	**Test Method Summary**	**Results**
Suturability	The suturability of Remplir™ was determined by performing suture pull out testing.	Test was completed and met specification. Like the predicate, the device has sufficient suture retention strength for its intended use.
Tensile Strength	Tensile strength was determined by placing the device between two grips and measuring the separation force required to reach device failure.	Test was completed and met specification. Like the predicate device, the tensile strength is suitable for intended use.

Biocompatibility	Biocompatibility testing was conducted in accordance with the requirements of ISO 10993	Biocompatibility studies have demonstrated Remplir™ to be non-cytotoxic, non-irritating, non-sensitizing, non-toxic, non- genotoxic, non-mutagenic, and non-pyrogenic
Sterilisation	The sterilization process was validated to achieve a sterility assurance level (SAL) of 10^{-6} per ISO 11137	Testing was completed and met specifications.
Endotoxin	The bacterial endotoxin validation testing was conducted per USP <85> and AAMI ST72	Testing was completed and met specification (USP<161>)
Rat transected sciatic nerve model	The device was surgically implanted around the transected sciatic nerve of the rat and compared to nerves wrapped with marketed predicate control material. Data were collected at 4, 12 and 24 weeks.	At all time points the changes observed in the nerve were similar between device and predicate control material and were typical of changes in a nerve after transection. At all time points the device was considered to elicit no or minimal reaction in comparison to the predicate control.

CONCLUSION

The intended use/indications for use, principles of operation, and technological characteristics of Remplir™ are substantially equivalent to the predicate device NeuraWrap™ (K041620). The safety, performance and effectiveness of Remplir™ for its intended use is demonstrated by bench and animal studies. Based on the evidence provided, the subject device, Remplir™ is substantially equivalent to the legally marketed predicate device, NeuraWrap™.