FDA 510(k) Premarket Notification

K243889 Remplir (ON-152, 15 x 20 mm)

CLEARED

Apr 2, 2025
105 days to decision

K243889 · Product code: **JXI** · Neurology
Source: https://www.510kdatabase.net/k243889/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Nerve (JXI)
Date received	Dec 18, 2024
Decision date	Apr 2, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Remplir (ON-203, 20 x 30 mm); Remplir (ON-304, 30 x 40 mm); Remplir (ON-405, 40 x 50 mm)

APPLICANT

Company	**Orthocell, Ltd.**
Location	Perth, AU
Contact	Kelly Hunter
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Kristin Zielinski Duggan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov