

K190756 IODOFLEXDec 20, 2019
270 days to decisionK190756 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190756/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Mar 25, 2019
Decision date	Dec 20, 2019
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Medical, Ltd.
Location	Hull, GB
Contact	Meenakshi Gupta
510(k) history	7 submissions · 7 cleared · 2016-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190756/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026