FDA 510(k) Premarket Notification

CLEARED

K143115 The VersaJet II Hydrosurgery System

Jul 15, 2015
258 days to decision

K143115 · Product code: **FQH** · General Hospital
Source: https://www.510kdatabase.net/k143115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lavage, Jet (FQH)
Date received	Oct 30, 2014
Decision date	Jul 15, 2015
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	Laura Reynolds
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...