

**K915359 PROMEON HYDROGEL DRESSING #45 STERILE W/
MESH**May 28, 1992
183 days to decisionK915359 · Product code: **NAE** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k915359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Hydrogel Without Drug And/or Biologic (NAE)
Date received	Nov 27, 1991
Decision date	May 28, 1992
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Vascular
Location	Walker, MI, US
Contact	DAVID MUELLER
510(k) history	475 submissions · 453 cleared · 1977-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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