

**K915358 PROMEON HYDROGEL DRESSING #45 NONSTERILE  
W/ MESH**Apr 28, 1992  
153 days to decisionK915358 · Product code: **KGX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k915358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tape And Bandage, Adhesive (KGX)
Date received	Nov 27, 1991
Decision date	Apr 28, 1992
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915358/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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