

K033291 TOPSEAL HEMOSTATIC DRESSING, MODEL 11150Mar 17, 2004
155 days to decisionK033291 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k033291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Oct 14, 2003
Decision date	Mar 17, 2004
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radi Medical Systems AB
Location	Uppsala, SE
Contact	HELENE EKSTRAND
510(k) history	24 submissions · 24 cleared · 1990-2013

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