

**K961775 PROFORE FOUR-LAYER BANDAGE SYSTEM KIT**Jul 16, 1996  
69 days to decisionK961775 · Product code: **EFQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k961775/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal (EFQ)
Date received	May 8, 1996
Decision date	Jul 16, 1996
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Smith &amp; Nephew United, Inc.</b>
Location	Largo, FL, US
Contact	JIM IRVIN
510(k) history	34 submissions · 23 cleared · 1989-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961775/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 1, 2026