

**K032893 SHELHIGH NO-REACT BIOCUFF**Dec 19, 2003  
93 days to decisionK032893 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k032893/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 17, 2003
Decision date	Dec 19, 2003
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shelhigh, Inc.</b>
Location	Union, NJ, US
Contact	SHLOMO GABBAY
510(k) history	8 submissions · 8 cleared · 1997-2003

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