

**K831886 FEMORAL CANAL SPONGE**Sep 12, 1983  
91 days to decisionK831886 · Product code: **NAB** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k831886/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze / Sponge,nonresorbable For External Use (NAB)
Date received	Jun 13, 1983
Decision date	Sep 12, 1983
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>Zimmer, Inc.</b>
Location	Warsaw, IN, US
Website	<a href="https://www.zimmerbiomet.com">https://www.zimmerbiomet.com</a>
510(k) history	374 submissions · 353 cleared · 1976-2026

Zimmer, Inc. is a leading orthopedic medical device manufacturer based in Warsaw, US. The company specializes in innovative surgical implants and trauma solutions. Zimmer, Inc. maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions since 1976. Orthopedic devices represent approximately 90% of the company's submission portfolio. The company remains actively engaged in product development, with the latest FDA 510(k) clearance in 2026. Recent cleared devices reflect the company's focus on joint reconstruction and trauma fixation. Notable ...

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