

**K000533 VOCOM IMPLANT- 8MM**Mar 1, 2000  
13 days to decisionK000533 · Product code: **MIX** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k000533/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Feb 17, 2000
Decision date	Mar 1, 2000
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Smith &amp; Nephew, Inc.</b>
Location	Mchenry, IL, US
Contact	ALICIA FARAGE
Website	<a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a>
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...

---