FDA 510(k) Premarket Notification

K091681 FINESS SINUS TREATMENT SYSTEM (ACCESS SHEATH COMPONENT)

CLEARED

Jul 8, 2009
28 days to decision

K091681 · Product code: **LRC** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k091681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jun 10, 2009
Decision date	Jul 8, 2009
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Entellus Medical, Inc.**
Location	Maple Grove, MN, US
Contact	DEBORAH I NEYMARK
510(k) history	27 submissions · 27 cleared · 2008-2022

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k091681/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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