

**K954989 DYONICS DISPOSABLE ENDOSCOPIC SURGERY
BLADES**Nov 27, 1995
27 days to decisionK954989 · Product code: ERL · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k954989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Oct 31, 1995
Decision date	Nov 27, 1995
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Dyonics, Inc.
Location	Andover, MA, US
Contact	DEBORAH J CONNORS
510(k) history	22 submissions · 19 cleared · 1990-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954989/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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