

K822367 TOTALSep 7, 1982
32 days to decisionK822367 · Product code: **LBN** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k822367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Total Ossicular, Prosthesis, Porous, Polyethylene (LBN)
Date received	Aug 6, 1982
Decision date	Sep 7, 1982
Days to decision	32 days
Third-party review	No

APPLICANT

Company	Treace Medical, Inc.
Location	Walker, MI, US
510(k) history	80 submissions · 80 cleared · 1982-1989

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Device record: <https://www.510kdatabase.net/k822367/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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