

**K771615 AUDI-SIL EARMOLD MATERIAL**Aug 30, 1977  
6 days to decisionK771615 · Product code: **ESH** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k771615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-pipe, Silicon Elastomer, Polyethylene, Polyurethane (ESH)
Date received	Aug 24, 1977
Decision date	Aug 30, 1977
Days to decision	6 days
Third-party review	No

**APPLICANT**

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Company	<b>Coe Laboratories, Inc.</b>
Location	Mchenry, IL, US
510(k) history	20 submissions · 20 cleared · 1976-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k771615/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 4, 2026