

**K831127 INTRA-ORAL ARTIFICIAL LARYNX**Jul 28, 1983  
113 days to decisionK831127 · Product code: **ESE** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k831127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Larynx, Artificial (battery-powered) (ESE)
Date received	Apr 6, 1983
Decision date	Jul 28, 1983
Days to decision	113 days
Third-party review	No

**APPLICANT**

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Company	<b>Xomed, Inc.</b>
Location	Arnold, MO, US
510(k) history	82 submissions · 81 cleared · 1976-2000

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