

**K965115 ROUND WINDOW CATH**Mar 10, 1997  
80 days to decisionK965115 · Product code: **ETD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k965115/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tympanostomy (ETD)
Date received	Dec 20, 1996
Decision date	Mar 10, 1997
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neuro-Biometrix, Inc.</b>
Location	Denver, CO, US
Contact	MICHAEL H ARENBERG
510(k) history	2 submissions · 2 cleared · 1997-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965115/> 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 5, 2026