FDA 510(k) Premarket Notification

K965115 ROUND WINDOW CATH

CLEARED

Mar 10, 1997
80 days to decision

K965115 · Product code: **ETD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k965115/

SUBMISSION DETAILS

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

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