

**K081440 BIVONA ADJUSTABLE AND FIXED NECKFLANGE
HYPERFLEX TRACHEOSTOMY TUBES**Sep 12, 2008
113 days to decisionK081440 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k081440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	May 22, 2008
Decision date	Sep 12, 2008
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smiths Medical Asd, Inc.
Location	Rockland, MA, US
Contact	BARBARA LAW
510(k) history	52 submissions · 52 cleared · 2004-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081440/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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