

K173280 Neonatal ConchaSmart Breathing CircuitsAug 2, 2018
290 days to decisionK173280 · Product code: **BZE** · Anesthesiology
Source: <https://www.510kdatabase.net/k173280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE)
Date received	Oct 16, 2017
Decision date	Aug 2, 2018
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflexmedical, Inc.
Location	Jeffrey, NH, US
Contact	Brian Gall
510(k) history	64 submissions · 61 cleared · 1985-2024

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