

K161376 DragonFly Surgical Drill SystemAug 25, 2016
99 days to decisionK161376 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k161376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	May 18, 2016
Decision date	Aug 25, 2016
Days to decision	99 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Grace Medical, Inc.
Location	Memphis, TN, US
Contact	William Graham
510(k) history	14 submissions · 14 cleared · 1994-2023

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