FDA 510(k) Premarket Notification

CLEARED

K190715 EndoRotor Console, EndoRotor Catheter, EndoRotor Specimen Trap, EndoRotor Filter Set, EndoRotor Roll Stand

Dec 13, 2019
269 days to decision

K190715 · Product code: **ERL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k190715/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Mar 19, 2019
Decision date	Dec 13, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Interscope, Inc.**
Location	Worchester, MA, US
Contact	Jeffery Ryan
510(k) history	4 submissions · 3 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	**Icon Clinical Research, LLC**
Contact	Cynthia Nolte

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov