FDA 510(k) Premarket Notification

K233958 hekaDrill

CLEARED

Mar 14, 2024
90 days to decision

K233958 · Product code: **ERL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k233958/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Dec 15, 2023
Decision date	Mar 14, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zethon, Ltd.**
Location	Aston Clinton, GB
Contact	Faith Robertson
510(k) history	2 submissions · 2 cleared · 2021-2024