

K213221 AMADEO, M-UK1015 (incl. attachments and accessories)May 26, 2022
239 days to decisionK213221 · Product code: ERL · Dental
Source: <https://www.510kdatabase.net/k213221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Sep 29, 2021
Decision date	May 26, 2022
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	W&H Dentalwerk Buermoss GmbH
Location	Burmoos, AT
Contact	Weidler Gerhard
510(k) history	2 submissions · 2 cleared · 2022-2023

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