FDA 510(k) Premarket Notification

K222368 MIST IC

CLEARED

Dec 1, 2022
118 days to decision

K222368 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k222368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 5, 2022
Decision date	Dec 1, 2022
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Imagine Milling Technologies, LLC**
Location	Chantilly, VA, US
Contact	Felix Chung
510(k) history	3 submissions · 3 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Kevin A Thomas

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