FDA 510(k) Premarket Notification

K213263 OnyxCeph

CLEARED

Jan 4, 2023
461 days to decision

K213263 · Product code: **LLZ** · Dental
Source: https://www.510kdatabase.net/k213263/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 30, 2021
Decision date	Jan 4, 2023
Days to decision	461 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Image Instruments GmbH**
Location	09123 Chemnitz, DE
Contact	Greg Holland
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Specialists, Inc.**
Contact	Greg Holland

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