

**K213263 OnyxCeph**Jan 4, 2023  
461 days to decisionK213263 · Product code: **LLZ** · Dental  
Source: <https://www.510kdatabase.net/k213263/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Specialists, Inc.</b>
Contact	Greg Holland

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

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