

K201546 OsOpia Synthetic Bone Void FillerOct 2, 2020
115 days to decisionK201546 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k201546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Jun 9, 2020
Decision date	Oct 2, 2020
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Revisios BV
Location	3723 Mb Bilthoven, NL
Contact	Hen Baron
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	MRC Global
Contact	Kathy Remsen

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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