

K190491 Blue Sky Bio Zygomatic Implant SystemAug 12, 2019
165 days to decisionK190491 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k190491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Feb 28, 2019
Decision date	Aug 12, 2019
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Blue Sky Bio, LLC
Location	Grayslake, IL, US
Contact	Michele Kupcso
510(k) history	16 submissions · 16 cleared · 2005-2024

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