

**K153064 Blue Sky Bio Zygomatic Implant System**Apr 29, 2016  
190 days to decisionK153064 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k153064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Oct 22, 2015
Decision date	Apr 29, 2016
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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