

**K191631 ZMAXX Dental Zirconia Blanks**Nov 1, 2019  
135 days to decisionK191631 · Product code: **EIH** · Dental  
Source: <https://www.510kdatabase.net/k191631/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Powder, Porcelain (EIH)            |
| Date received         | Jun 19, 2019                       |
| Decision date         | Nov 1, 2019                        |
| Days to decision      | 135 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Zmaxx Bioceramics, LLC</b>         |
| Location       | Foster, CA, US                        |
| Contact        | Josef Wu                              |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

**REGULATORY CONSULTANT**

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|-----------------|-------------------------------------|
| Consulting firm | <b>Mid-Link Consulting Co, Ltd.</b> |
| Contact         | Ying Xu                             |

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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