

**K182338 Blue Sky Bio Computerized Orthodontic Bracket System**Nov 9, 2018  
73 days to decisionK182338 · Product code: **DYW** · Dental  
Source: <https://www.510kdatabase.net/k182338/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Bracket, Plastic, Orthodontic (DYW) |
| Date received         | Aug 28, 2018                        |
| Decision date         | Nov 9, 2018                         |
| Days to decision      | 73 days                             |
| Third-party review    | Yes                                 |
| Combination product   | No                                  |
| PCCP authorized       | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Blue Sky Bio</b>                   |
| Location       | Irvine, CA, US                        |
| Contact        | Albert Zickmann                       |
| 510(k) history | 5 submissions · 5 cleared · 2000-2018 |

**REGULATORY CONSULTANT**

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|-----------------|--------------------------------------|
| Consulting firm | <b>Third Party Review Group, LLC</b> |
| Contact         | DAVE YUNGVIRT                        |

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/k182338/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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