

**K201919 Blue Sky Bio TAD**Dec 17, 2020  
160 days to decisionK201919 · Product code: **OAT** · Dental  
Source: <https://www.510kdatabase.net/k201919/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Jul 10, 2020
Decision date	Dec 17, 2020
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201919/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026