

**K192522 TSV BellaTek Express and BellaTek Flex Abutments**Dec 9, 2019  
87 days to decisionK192522 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k192522/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 13, 2019
Decision date	Dec 9, 2019
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet 3i, LLC</b>
Location	Palm Beach Gardens, FL, US
Contact	Krupal Patel
510(k) history	7 submissions · 7 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192522/> 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 26, 2026