

**K190353 Bfit Sleep, Bfit Sleep with DentiTrac, Bfit Engage, Bfit Engage with DentiTrac**Apr 10, 2020  
420 days to decisionK190353 · Product code: PLC · Dental  
Source: <https://www.510kdatabase.net/k190353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleep Appliances With Patient Monitoring (PLC)
Date received	Feb 15, 2019
Decision date	Apr 10, 2020
Days to decision	420 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Residential Home Sleep Services</b>
Location	Battle Creek, MI, US
Contact	Chris Gillette
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190353/> 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 June 29, 2026