

K150369 SomnoDent Classic with DentiTrac Micro-recorder, SomnoDent Flex with DentiTrac Micro-recorder, SomnoDent Herbst Advance (Classic or Flex Retention) with DentiTrac Micro-recorder, SomnoDent G2 (Classic or Flex Retention) with DentiTrac Micro-recorder, SomnoDent Fusion (Classic or Flex Retention) with DentiTrac Micro-recorderJun 18, 2015
125 days to decisionK150369 · Product code: PLC · Dental
Source: <https://www.510kdatabase.net/k150369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleep Appliances With Patient Monitoring (PLC)
Date received	Feb 13, 2015
Decision date	Jun 18, 2015
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Somnomed, Inc.
Location	Denton, TX, US
Contact	KIEN T. NGUYEN
510(k) history	10 submissions · 10 cleared · 2008-2024

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