

**K220907 The iNAP One Sleep Therapy System**Jun 16, 2023  
444 days to decisionK220907 · Product code: **OZR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k220907/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intraoral Pressure Gradient Device (OZR)
Date received	Mar 29, 2022
Decision date	Jun 16, 2023
Days to decision	444 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Somnics, Inc.</b>
Location	Hsinchu County, TW
Contact	Chung-Chu Chen
510(k) history	2 submissions · 2 cleared · 2016-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ivdd Regulatory Consultant</b>
Contact	Feng-Yu Lee

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/k220907/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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