

K193460 The iNAP One Sleep Therapy SystemMay 26, 2020
162 days to decisionK193460 · Product code: **OZR** · Anesthesiology
Source: <https://www.510kdatabase.net/k193460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intraoral Pressure Gradient Device (OZR)
Date received	Dec 16, 2019
Decision date	May 26, 2020
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Somnice, Inc.
Location	Hsinchu County, TW
Contact	Sujith Shetty
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Maxis, LLC
Contact	Sujith Shetty

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT02324790**Pilot Study of Negative Pressure Sleep Therapy System to Treat Obstructive Sleep Apnea**

Status	Terminated - <i>No results published to ClinicalTrials.gov</i>
Enrollment	34 patients (actual)
Study sites	4 sites
Condition studied	Obstructive Sleep Apnea
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 13, 2016
Sponsor	Somnics, Inc. (Industry)

Primary outcome

Change from baseline of Apnea-Hypopnea Index (AHI)

Secondary outcome

Change from baseline of obstructive apnea reduction

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02324790