

K180619 BongoAug 16, 2018
160 days to decisionK180619 · Product code: **OHP** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k180619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Expiratory Resistance Valve, Intranasal, For Obstructive Sleep Apnea (OHP)
Date received	Mar 9, 2018
Decision date	Aug 16, 2018
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innomed Healthscience, Inc.
Location	Deerfield Beach, FL, US
Contact	Javier Collazo
510(k) history	1 submissions · 1 cleared · 2018-2018

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