

**K203606 Serena Sleep Block Mandibular Advancement (BMA),
Serena Sleep Elastic Mandibular Advancement (EMA)**Mar 10, 2021
90 days to decisionK203606 · Product code: LRK · Dental
Source: <https://www.510kdatabase.net/k203606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Dec 10, 2020
Decision date	Mar 10, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meris Investment Group
Location	Lakeland, MN, US
Contact	Gary Maas
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Medavice, Inc.
Contact	Sarah Moss

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203606/>; Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026