

K252043 Bipolar applicator CelonProBreath (WB990310)Sep 23, 2025
85 days to decisionK252043 · Product code: **GEI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k252043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 30, 2025
Decision date	Sep 23, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Bipolar applicator CelonProSleep plus (WB990311); Bipolar applicator CelonProBreath (WB990210); Bipolar applicator CelonProSleep plus (WB990211)

APPLICANT

Company	Olympus Winter & Ibe GmbH
Location	Melville, NY, US
Contact	Michaela Soukopova
510(k) history	42 submissions · 42 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Technologies America
Contact	Teffany Hutto

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

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