

K193356 BiZact Tonsillectomy Device Advanced Bipolar Tissue Sealer/DividerMar 2, 2020
89 days to decisionK193356 · Product code: **GEI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k193356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 4, 2019
Decision date	Mar 2, 2020
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Juma Hoshino
510(k) history	89 submissions · 86 cleared · 2010-2026

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