

K233859 BASIS FLOW IIMar 5, 2024
90 days to decisionK233859 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k233859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Dec 6, 2023
Decision date	Mar 5, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	YAMAHACHI DENTAL MFG., Co.
Location	Gamagori, JP
Contact	Masashi Toyama
510(k) history	3 submissions · 3 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	Globizz Corporation
Contact	Takahiro Haruyama

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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