

K190790 Flex FitJul 31, 2020
492 days to decisionK190790 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k190790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Mar 27, 2019
Decision date	Jul 31, 2020
Days to decision	492 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dk Mungyo Corporation
Location	Gimhae-Si, KR
Contact	Kang Nae In
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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