

K182118 armor LCMay 3, 2019
270 days to decisionK182118 · Product code: **EIE** · Dental
Source: <https://www.510kdatabase.net/k182118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dam, Rubber (EIE)
Date received	Aug 6, 2018
Decision date	May 3, 2019
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mavrik Dental Systems, Ltd.
Location	Raanana, IL
Contact	Sherwyn Davidson
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Heyer Regulatory Solutions, LLC
Contact	Sherwyn Davidson

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182118/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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