

K220894 SmileGuardJun 10, 2022
74 days to decisionK220894 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k220894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Mar 28, 2022
Decision date	Jun 10, 2022
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Envisiontec GmbH
Location	Gladbeck, DE
Contact	Ruediger Van Bernum
510(k) history	5 submissions · 5 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Qserve Group, Us, Inc.
Contact	Patsy J Trisler

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

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