

K201173 E-GuardNov 27, 2020
210 days to decisionK201173 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k201173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	May 1, 2020
Decision date	Nov 27, 2020
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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