

K251252 NOBILCAM IMPAK DiscAug 1, 2025
100 days to decisionK251252 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k251252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Apr 23, 2025
Decision date	Aug 1, 2025
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Huge Dental Material Corporation
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	8 submissions · 8 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251252/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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