

K230237 Dental Braces (Model: HK-Y-0.4, HK-Y-0.45, HK-Y-0.63, HK-Y-0.7, HK-Y-ST-0.76, HK-Y-CF-0.76, HK-Y-0.9, HK-Y-1.0, HK-Y-2.0)Sep 14, 2023
227 days to decisionK230237 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k230237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jan 30, 2023
Decision date	Sep 14, 2023
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Hkable 3D Biologic Printing Technology(Chongqing) Co., Ltd.
Location	Chongqing, CN
Contact	Chen Yang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230237/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026