

K202855 Orthodontic FacemaskJun 21, 2021
266 days to decisionK202855 · Product code: **DZB** · Dental
Source: <https://www.510kdatabase.net/k202855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Headgear, Extraoral, Orthodontic (DZB)
Date received	Sep 28, 2020
Decision date	Jun 21, 2021
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Ita.O Italian Orthodontic System S.R.L.
Location	Villanova Di Castenaso, IT
Contact	Alessandra Ferroni
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	THEMA S.r.l.
Contact	Marisa Testa

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/k202855/> 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 27, 2026