

K202278 OBS Anchorage Screw, Biokey Anchorage ScrewJan 8, 2021
150 days to decisionK202278 · Product code: **OAT** · Dental
Source: <https://www.510kdatabase.net/k202278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Aug 11, 2020
Decision date	Jan 8, 2021
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bomei Co, Ltd.
Location	Taoyuan City, TW
Contact	Steven Pan
510(k) history	2 submissions · 2 cleared · 2016-2021

REGULATORY CONSULTANT

Consulting firm	Voler Biotech Consulting CO., Ltd.
Contact	Chih-Hao Kao

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

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