

K180718 ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIESOct 30, 2018
225 days to decisionK180718 · Product code: **DYW** · Dental
Source: <https://www.510kdatabase.net/k180718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Plastic, Orthodontic (DYW)
Date received	Mar 19, 2018
Decision date	Oct 30, 2018
Days to decision	225 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tomy, Inc.
Location	Bradenton, FL, US
Contact	Jinichi Watanabe
510(k) history	4 submissions · 4 cleared · 2012-2018

REGULATORY CONSULTANT

Consulting firm	Regulatory & Quality Solutions, Inc.
Contact	Ruthanne Vendy

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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