FDA 510(k) Premarket Notification

K101676 CLEARARCH

CLEARED

Sep 13, 2010
90 days to decision

K101676 · Product code: **DYW** · Dental
Source: https://www.510kdatabase.net/k101676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Plastic, Orthodontic (DYW)
Date received	Jun 15, 2010
Decision date	Sep 13, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ormco Corp.**
Location	Mchenry, IL, US
Contact	Wendy Garman
510(k) history	40 submissions · 39 cleared · 1978-2014