

K180404 3M Clarity Ultra Self-Ligating Brackets and Adhesive Coated Appliance SystemMar 16, 2018
30 days to decisionK180404 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k180404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Feb 14, 2018
Decision date	Mar 16, 2018
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3M Healthcare
Location	St. Paul, MN, US
Contact	Lam Duong
510(k) history	21 submissions · 20 cleared · 1991-2020

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	MARK JOB

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/k180404/>; 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 June 28, 2026