

K180241 Orthocaps TwinalignerSep 28, 2018
242 days to decisionK180241 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k180241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jan 29, 2018
Decision date	Sep 28, 2018
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Caps GmbH
Location	Hamm 59069, DE
Contact	Wajeeh Khan
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Rmo, Inc.
Contact	Angelica Ayala

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

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