

K122065 DIGITAL IMPRESSION SYSTEM FOR ORTHODONTIC USEFeb 8, 2013
210 days to decisionK122065 · Product code: **NOF** · Dental
Source: <https://www.510kdatabase.net/k122065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Optical Impression, Computer Assisted Design And Manufacturing (cad/cam) Of Dental Restorations (NOF)
Date received	Jul 13, 2012
Decision date	Feb 8, 2013
Days to decision	210 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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