

**K211308 INNI-CERA**Oct 4, 2021  
158 days to decisionK211308 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k211308/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Apr 29, 2021
Decision date	Oct 4, 2021
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aon Co., Ltd.</b>
Location	Gunpo, KR
Contact	Julie Choi
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>E &amp; M</b>
Contact	Sanghwa Myung

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211308/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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