

**K191304 EthanZir Zirconia**Nov 4, 2019  
174 days to decisionK191304 · Product code: **EIH** · Dental  
Source: <https://www.510kdatabase.net/k191304/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	May 14, 2019
Decision date	Nov 4, 2019
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Besorah Dental Solutions NZ Limited</b>
Location	Auckland, NZ
Contact	Jobin Jose
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Rac Corporation</b>
Contact	Robin A. Carden

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

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