

**K011491 HELIOSEAL CLEAR CHROMA**Aug 16, 2001  
93 days to decisionK011491 · Product code: **EBC** · Dental  
Source: <https://www.510kdatabase.net/k011491/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	May 15, 2001
Decision date	Aug 16, 2001
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ivoclar North America, Inc.</b>
Location	Amherst, NY, US
Contact	ANDERJEET GULATI
510(k) history	131 submissions · 131 cleared · 1989-2001

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