

**K060530 SD CERAMIC COPING FOR QUICK ABUTMENT,  
LOCKING. MODEL 45301. RD CERAMIC COPING FOR QUICK  
ABUTMENT, LOCKING, MODEL 45302.**May 22, 2006  
83 days to decisionK060530 · Product code: ELL · Dental  
Source: <https://www.510kdatabase.net/k060530/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Teeth, Porcelain (ELL)
Date received	Feb 28, 2006
Decision date	May 22, 2006
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lifecore Biomedical, Inc.</b>
Location	Washington, DC, US
Contact	RACHEL KENNEDY
Website	<a href="http://www.lifecore.com/">http://www.lifecore.com/</a>
510(k) history	34 submissions · 34 cleared · 1991-2007

Lifecore Biomedical, Inc. is a sterile injectable contract development and manufacturing organization (CDMO) and sodium hyaluronate producer with a manufacturing facility in Washington, US. The company specializes in formulation development, aseptic fill-finish, analytical testing, and stability services for pharmaceutical and medical device manufacturers. Lifecore received FDA 510(k) clearances from total submissions, with clearances spanning 1991 to 2007. The company's regulatory focus was predominantly Dental devices, representing 97% of submissions. This includes dent...