

**K050506 PRIMASOLO ONE-PIECE IMPLANTS & HEALING CAPS**Apr 15, 2005  
46 days to decisionK050506 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k050506/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 28, 2005
Decision date	Apr 15, 2005
Days to decision	46 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...

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