

**K072768 RESTORE, STAGE-1, RENOVA PRIMASOLO AND  
PRIMACONNEX DENTAL IMPLANTS**Oct 23, 2007  
25 days to decisionK072768 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k072768/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 28, 2007
Decision date	Oct 23, 2007
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lifecore Biomedical, Inc.</b>
Location	Washington, DC, US
Contact	KAREN CLEMENT
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k072768/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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