

**K013935 ALLOFIT ACETABULAR SYSTEM 32MM ALPHA
DURASUL INSERTS**Dec 13, 2001
15 days to decisionK013935 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k013935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Nov 28, 2001
Decision date	Dec 13, 2001
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sulzer Orthopedics, Inc.
Location	Austin, TX, US
Contact	MITCHELL A DHORITY
510(k) history	45 submissions · 41 cleared · 1997-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013935/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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