FDA 510(k) Premarket Notification

K082079 REGEN COLLAGEN SCAFFOLD (CS)

CLEARED

Dec 18, 2008
148 days to decision

K082079 · Product code: **OLC** · Orthopedic
Source: https://www.510kdatabase.net/k082079/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaffold, Partial Medial Meniscal Defects Extending Into The Red/white Zone, Resorbable Bovine Collagen (OLC)
Date received	Jul 23, 2008
Decision date	Dec 18, 2008
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Regen Biologics, Inc.**
Location	Hackensack, NJ, US
Contact	JOHN DICHIARA
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k082079/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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