

K140844 BIOSPHERE BIOACTIVE BONE GRAFT PUTTY, 2.5CC, 5CC, 10CC

Jul 16, 2014
105 days to decision

K140844 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k140844/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Apr 2, 2014
Decision date	Jul 16, 2014
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synergy Biomedical, Inc.
Location	Washington, DC, US
Contact	RANDY PREBULA
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k140844/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026