

**K081758 HEALOS FX INJECTABLE BONE GRAFT  
REPLACEMENT, MODELS 276175002, 276175005, 276175010,  
276175015**Sep 3, 2008  
75 days to decisionK081758 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k081758/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jun 20, 2008
Decision date	Sep 3, 2008
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Depuy Spine, Inc.</b>
Location	Raynham, MA, US
Contact	HANDE TUFAN
510(k) history	68 submissions · 67 cleared · 2004-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081758/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026