FDA 510(k) Premarket Notification

K061880 ACCELI DBM FAMILY PRODUCTS, 0.5CC, 1CC, 2.5CC, 5CC, 10CC, 15CC, 30CC

CLEARED

Aug 15, 2007
408 days to decision

K061880 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k061880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jul 3, 2006
Decision date	Aug 15, 2007
Days to decision	408 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Isotis NV**
Location	North Attleboro, MA, US
Contact	ELAINE SCHUTTE
510(k) history	8 submissions · 8 cleared · 2000-2007