FDA 510(k) Premarket Notification

K070181 SINTEA BIOTECH DSC/ALF SPINAL SYSTEM, DSC.XX.T5.XX, ALF.XX.T5.XX

CLEARED

Apr 18, 2007
89 days to decision

K070181 · Product code: **MQP** · Orthopedic
Source: https://www.510kdatabase.net/k070181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Jan 19, 2007
Decision date	Apr 18, 2007
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sintea Biotech, Inc.**
Location	Miami Beach, FL, US
Contact	GUSTAVO A RIOS
510(k) history	10 submissions · 10 cleared · 2002-2009