FDA 510(k) Premarket Notification

K071473 MODIFICATION TO SUPERDIMENSION/BRONCHUS PREMIUM 2

CLEARED

Jul 12, 2007
44 days to decision

K071473 · Product code: **EOQ** · Radiology
Source: https://www.510kdatabase.net/k071473/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	May 29, 2007
Decision date	Jul 12, 2007
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Superdimension, Ltd.**
Location	Hasbrouck Heights, NJ, US
Contact	CLAY ANSELMO
510(k) history	10 submissions · 10 cleared · 2004-2010