FDA 510(k) Premarket Notification

K070648 THE INHIBITOR, MODEL 001

CLEARED

Jun 29, 2007
113 days to decision

K070648 · Product code: **KLW** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k070648/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Mar 8, 2007
Decision date	Jun 29, 2007
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Melmedtronics, Inc.**
Location	Hurst, TX, US
Contact	DAVID W HOLMES
510(k) history	1 submissions · 1 cleared · 2007-2007