FDA 510(k) Premarket Notification

K140782 ULTRAMIST SYSTEM, ULTRAMIST GENERATOR, ULTRAMIST TREATMENT WAND, ULTRAMIST APPLICATOR

CLEARED

Aug 13, 2014
135 days to decision

K140782 · Product code: **NRB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k140782/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Cleaner, Ultrasound (NRB)
Date received	Mar 31, 2014
Decision date	Aug 13, 2014
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Celleration, Inc.**
Location	Eden Prairie, MN, US
Contact	KATHY SIMPSON
510(k) history	3 submissions · 3 cleared · 2005-2014