FDA 510(k) Premarket Notification

K182082 Tumark for Eviva, Tumark for Brevera

CLEARED

Oct 31, 2018
90 days to decision

K182082 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182082/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Aug 2, 2018
Decision date	Oct 31, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Somatex Medical Technologies GmbH**
Location	Cambridge, MA, US
Contact	Burkhard Jakob
510(k) history	7 submissions · 7 cleared · 2008-2021