

K180443 Tumark VisionMar 22, 2018
30 days to decisionK180443 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Feb 20, 2018
Decision date	Mar 22, 2018
Days to decision	30 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

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