K080507 AOC POROUS POLYETHYLENE, AOC POROUS HDPE, AOC POROUS POLYETHYLENE SURGICAL IMPLANT

CLEARED

Apr 21, 2008
56 days to decision

K080507 · Product code: **KKY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k080507/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Feb 25, 2008
Decision date	Apr 21, 2008
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ceremed , Inc.**
Location	Los Angeles, CA, US
Contact	TADEUSZ WELLISZ
510(k) history	20 submissions · 20 cleared · 2004-2016