



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	398171	Alma Lasers Australia Pty Ltd - Soprano Titanium - Multi-modality skin surface treatment system
ARTG entry for	Medical Device Included Class IIb	
Sponsor	Alma Lasers Australia Pty Ltd	
Postal Address	G01 184 Bourke Road, Alma Lasers, Alexandria, NSW, 2015 Australia	
ARTG Start Date	21/10/2022	
Product Category	Medical Device Class IIb	
Status	Active	
Approval Area	Medical Devices	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Alma Lasers GmbH	Nordostpark 100-102 , Nuernberg, 90411 Germany

Products

1 . Soprano Titanium - Multi-modality skin surface treatment system			
Product Type	Medical device system	Effective Date	21/10/2022
GMDN	45220 Multi-modality skin surface treatment system		
Intended Purpose	dermatologic and aesthetic procedures requiring selective photothermolysis for hair removal and to effect stable, long-term hair reduction using laser energy. Temporary relief of minor muscle pain and joint pain, skin laxity through deep heating with near infra-red radiation		

Specific Conditions
No Specific Conditions included on Record

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