



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	329940	Alma Lasers Australia Pty Ltd - Skin contouring system, radio-frequency
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	14/02/2020	
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 . Skin contouring system, radio-frequency

Product Type	Single Device Product	Effective Date	14/02/2020
GMDN	45219 Skin contouring system, radio-frequency		
Intended Purpose	The UniLarge and CoaxiPolar modules are intended for the following indications: acne vulgaris, acne scars, acne rosacea, body and face contouring, cellulite, skin laxity, rhytids and wrinkles, skin tightening and relief of pain		

Specific Conditions

No Specific Conditions included on Record

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