Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	411514	AMO Australia Pty Ltd - TECNIS Synergy™ OptiBlue™ IOL with TECNIS Simplicity™ Delivery System - Lens, intraocular, posterior chamber

ARTG entry for	Medical Device Included Class III
Sponsor	AMO Australia Pty Ltd
Postal Address	PO Box 134, North Ryde, NSW, 1670 Australia
ARTG Start Date	28/06/2023
Product Category	Medical Device Class III
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
Johnson & Johnson Surgical Vision Inc	31 Technology Drive Suite 200 , Irvine CA, 92618 United States Of America

Products

1 . TECNIS Synergy™ OptiBlue™ IOL with TECNIS Simplicity™ Delivery System - Lens, intraocular, posterior chamber

Product Type	Single Device Product	**Effective Date**	28/06/2023

GMDN	35658 Lens, intraocular, posterior chamber
Functional Description	The device, model DFR00V, contains a foldable acrylic 1-piece ultraviolet and violet light-filtering IOL, intended to provide high-quality vision over a full range of distances, including far, intermediate and near to increase spectacle independence. It is designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. The Delivery System is designed to provide a sterile, controlled and touch-free method of delivering the lens into the eye.
Intended Purpose	The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Synergy™ OptiBlue™ IOL which is indicated for primary implantation for the visual correction of: [1] aphakia in adults in whom a cataractous lens has been removed, and [2] aphakia following refractive lensectomy in presbyopic adults who may benefit from useful near vision and reduced spectacle dependence across a range of distances. The lens is intended to be placed in the capsular bag.
Variant information	Diopter +5.0D to +34.0D

Specific Conditions

No Specific Conditions included on Record

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