Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	158585 Dynek Pty Ltd - Radene - Suture, polyvinylidene fluoride
ARTG entry for	Medical Device Included Class III
Sponsor	Dynek Pty Ltd
Postal Address	PO Box 2346, PORT ADELAIDE, SA, 5015 Australia
ARTG Start Date	19/01/2009
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
Dynek Pty Ltd	9 Circuit Drive HENDON, SA, 5014 Australia

Products

1 . Radene - Suture, polyvinylidene fluoride

Product Type	Single Device Product	**Effective Date**	19/01/2009
GMDN	38873 Suture, polyvinylidene fluoride		
Functional Description	Suture, non-absorbable, synthetic, monofilament, yellow, with surgeon able to choose appropriate thread diameter and length according to surgical requirement		
Intended Purpose	Surgical procedures for tying off, ligation and/or tissue approximation		
Variant information	Length (cm) 10 - 250 Diameter (mm) 0.001 - 0.999		

Specific Conditions

No Specific Conditions included on Record