Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	345090 Connexion Surgical Pty Ltd - MagnetOs Putty - Bone matrix implant, synthetic
ARTG entry for	Medical Device Included Class III
Sponsor	Connexion Surgical Pty Ltd
Postal Address	12 Finch Avenue, Concord, NSW, 2137 Australia
ARTG Start Date	30/09/2020
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
Kuros Biosciences BV	Professor Bronkhorstlaan 10 , MB Bilthoven, 3723 Netherlands

Products

1 . MagnetOs Putty - Bone matrix implant, synthetic

Product Type	Single Device Product	**Effective Date**	30/09/2020
GMDN	17751 Bone matrix implant, synthetic		
Functional Description	MagnetOs Putty is a synthetic Tri-Calcium Phosphate and Hydroxyapatite resorbable micro-structured bone void filler for the repair of bony defects. The product consists of granules, premixed with a synthetic polymeric binder that provides cohesion between the granules. MagnetOs Putty has a porous trabecular structure that resembles the interconnected porosity of human cancellous bone.		
Intended Purpose	MagnetOs Putty is intended for use as bone void filler for voids and gaps that are not intrinsic to the stability of the bony structure. MagnetOs Putty is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. MagnetOs Putty is intended to be packed into bony voids or gaps of the skeletal system (i.e. extremities, spine, cranial, mandible, maxilla and pelvis) and may be combined with autogenous bone.		
Variant information	Size 250-2000um Volume (mL) 0.5-20		

Specific Conditions

No Specific Conditions included on Record

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