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Section 2 - Summary of Safety and Effectiveness and Class III Certification and Summary

a. Summary Of Safety And Effectiveness

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Device Name
Guglielmi Detachable Coil (GDC), Class III.

Device Description
The GDC system consists of a remote power supply and an occlusion coil attached to a delivery wire. The occlusion coil is detached by electrolytically dissolving a small portion of the delivery wire upon desired placement of the coil in the anatomy. The occlusion coils are manufactured from a platinum wire which is wound into a primary coil, and formed into a secondary helical or curved shape. The delivery wire consists of a stainless steel core wire with a stainless steel coil soldered on at the distal end and a Teflon outer jacket proximal to the detachment zone.

Intended Use
The Guglielmi Detachable Coil (GDC) is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be: a)very high risk for management by traditional operative techniques, or, b) inoperable, and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature. The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.

Predicate Devices

Target Therapeutics intends to expand the indications for use for the GDC Guglielmi Detachable Coil. The GDC is currently cleared for use in intracranial aneurysms and other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature (K951256, K960705). The purpose of this submission is to expand the indications to include peripheral indications.

Indications for Use Comparison Chart

GDC with expanded indications	for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be a)very high risk for management by traditional operative techniques, or b) inoperable, and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature. The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.
GDC (K951256, K960705)	for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be a)very high risk for management by traditional operative techniques, or b) inoperable , and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature.
Target Platinum Occlusion Coils (.018 and .010)	to obstruct or reduce the rate of blood flow in the peripheral and neuro vasculature for the interventional management of AVM and AVF when devascularization prior to definitive surgical resection is required
Target .035 Platinum Occlusion Coils	for arterial and venous embolizations in the peripheral vasculature.
COOK OCCLUSION COILS	.018": for embolization of selective vessel supply to arteriovenous malformations and other vascular lesions of the brain, spinal cord, spine and other small vessel applications. .035": for arterial and venous embolizations
ARTIFICIAL EMBOLIZATION DEVICE (CFR 21 Section 882.5950)	*Identification*: An artificial embolization device is an object that is placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation.