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a. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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DEVICE NAME:

Berenstein Coil , Class III

DEVICE DESCRIPTION:

The Berenstein Coil is an occlusion coil designed to be delivered by injection through either Target Therapeutics Infusion Catheters or Balt Magic 1.5F and 1.8F catheters. These coils are radiopaque.

The Berenstein Coil is available in a helical shape, in 0.008 or 0.016 inch primary wind diameter (Berenstein Coil - 10 and Berenstein Coil - 18, respectively), and in a variety of lengths. The Berenstein Coil comes loaded in a sheath-like introducer for easy transfer into a catheter.

An adapter, manufactured by Target Therapeutics, is required when Berenstein Coil - 10 Occlusion Devices are used with Balt Magic catheters. The Adapter may be supplied with the Berenstein Coil or may be available separately.

INTENDED USE:

Berenstein Coils are intended for the embolization of vascular malformations of the neuro vasculature.

PREDICATE DEVICES:

The Berenstein Coil is substantially equivalent in materials, intended use, performance, and design parameters to Target Therapeutics Platinum Occlusion Coils. It is equivalent in the method of delivery to Cook Embolization Coils. All predicate devices are currently cleared for commercial distribution. The only difference between the Berenstein Coils and the predicates is the outer diameter of the platinum wire. In instances where the technological characteristics are different, it has been demonstrated with in-vivo and in-vitro testing that there are no new questions raised regarding safety or efficacy of the Berenstein Coil.

**TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE
DETERMINATION:**

In-vitro, in-vivo, and biocompatibility testing was performed to demonstrate that the Berenstein Coil is as safe, as effective, and performs as well as or better than the predicate device.

Functional bench testing was comprised of: 1) force required to deliver coils through catheters, and 2) coil/catheter compatibility. The results of these tests showed the Berenstein Coil is substantially equivalent to the predicate device.