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510(K) SUMMARY

1. SUBMITTER:

Innovasive Devices, Inc.
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Contact: Eric Bannon, Vice President of Quality Assurance and Regulatory Affairs
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2. DEVICE:

Innovasive 2.8mm x 6.4mm ROClet
Classification Name: Single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices ROClet

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Innovasive Devices ROClet was the 2mm GORE-TEX soft tissue patch, produced by W.L. Gore, Flagstaff, AZ.

4. DEVICE DESCRIPTIONS:

The ROClet product consists of the implantable ROClet, an insertion instrument and an awl. The ROClet will be offered as a sterile single use device. The insertion instrument and awl will be offered as a non-sterile reusable instrument.

The ROClet consists of a molded component 2.8mm in diameter and 6.4mm long with a flange at one end and barbs along its length. The flange is intended to rest of the humeral head bone surface. The barbs are used to keep the device in place only until the suture is tied during the repair procedure. The ROClet is fitted with a nylon suture threader assembly placed in the ID of the device and is used to pass the sutures used during the tunnel procedure down the center of the ROClet until it is eventually tied during the repair.

The ROClet and suture threader assembly will be in a holding cartridge when received by the surgeon. The device is loaded onto the insertion instrument and removed from the cartridge. The sutures exiting the bone tunnel already established to repair the rotator cuff is passed through the suture threader assembly. The suture threader assembly with the suture is then withdrawn from the back of the ROClet and discarded. This results in the suture exiting the bone tunnel now passing through the center of the ROClet device and exiting the back

of the device at its flanged end. If needed, the awl can be used to size the bone tunnel. This ensures the device works with all methods used to create a bone tunnel.

The ROClet, still on the insertion tool is then manually pressed into the bone tunnel. The ribbed end of the ROClet, now in the tunnel, aids in keeping the device in place while the end of the suture exiting the device is tied off and the repair completed. The tied suture ensures the device remains in place in the bone tunnel hole until the bone to tissue interface heals. One ROClet is used for each bone tunnel.

5. INTENDED USE:

The intended use of the ROClet is to protect the suture during its use in transosseous bone tunneling in the repair of rotator cuff tears of the shoulder.

6. COMPARISON OF CHARACTERISTICS:

The Innovasive Devices ROClet is comprised of acetal plastic. This device is used to protect suture when used to complete a repair of the rotator cuff through the use of transosseous bone tunnels. The ROClet is placed into the bone tunnel and the suture passed through its center. This protects the suture from damage from the surrounding hole and prevents migration of the suture through the bone. An inserter is used to place the device and an awl is used to ensure each bone tunnel is appropriately sized to receive the device.

The 2mm GORE-TEX soft tissue patch is a square of material constructed of Gore-tex which is used as a pladget. The material is used to augment the strength of the bone and surrounding tissue by more evenly distributing the load from the sutures over a wider area.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Bone model testing: Comparison of the ultimate strength of suture with and without the ROClet placed in the bone tunnel. In addition, the cyclic loading with the device was characterized.