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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 and 3.5mm ROC Suture Bone Fastener
Classification Name: Single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices ROC Suture Bone Fastener

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Innovasive Devices 2.8mm and 3.5mm Roc Suture Bone Fastener was the Mitek GII Anchor, marketed by Mitek Surgical, Norwood, MA.

4. DEVICE DESCRIPTIONS:

The Innovasive ROC Suture Bone Fastener is an implantable soft tissue fixation device complete with the instrumentation needed to effect soft tissue to bone repair. The devices consist of a high density polyethylene cartridge with an acetyl drive pin which is deployed into a pre-drilled hole in the bone. The Fastener is deployed through the use of a deployment handle made of molded polysulfone. The Fastener also has a stainless steel drive tool inside the cartridge which shears the implantable Fastener when deployed by the handle. The Fastener comes with various non-absorbable suture material.

In addition to the Fastener, a stainless steel drill and drill guide is available to establish the proper hole for in the bone for the Fastener. A stainless steel and polysulfone extractor is included which can be used to remove the deployed Fastener should it be necessary. All of the instrumentation except the Fastener will be offered as reusable devices and can be autoclaved in the sterilization tray provided for this purpose.

The Fastener will be available as a sterile, single use device. Both sutured and sutureless versions will be marketed.

5. INTENDED USE:

The ROC fastener is intended for bladder neck suspension for female urinary incontinence due to urethral hypermobility.

6. COMPARISON OF CHARACTERISTICS:

The Innovasive Devices ROC Suture Bone Fastener is comprised of two polymer components, high density polyethylene and acetyl plastic. This device is used to secure suture in a predrilled hole in bone. It remains fixed in the bone through radial compression as the device is deployed. This remains true for all sizes of the device.

The Mitek Mini Anchor is comprised of titanium with nitinol arcs. The arcs are imbedded in bone when placed in the predrilled hole. The intended use of the Mitek GII Anchor and the Innovasive ROC Fasteners are identical.

7. PERFORMANCE DATA:

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

1. Cadaver study: Comparison of the ultimate holding strength in the bone indicated compared to the predicate device. The Innovasive Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate device at a .01 significance level.