

K964945
510(k) SUMMARY

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1. SUBMITTER:

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2. DEVICE:

Innovasive 3.5mm ROC XS 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 3.5mm ROC XS Suture Bone Fastener was the Innovasive 3.5mm ROC Suture Bone Fastener

4. DEVICE DESCRIPTIONS:

The Innovasive Rotator Cuff 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 three component system comprised entirely of acetal plastic. The Fastener is deployed through the use of a deployment handle made of molded polysulfone. The Fastener is deployed into the bone by causing a crown component to cam over a stationary anvil causing the fingers of the device to spread. The Fastener comes with various non-absorbable suture material.

In addition to the Fastener, a stainless steel drill, drill guide and awl are available to establish the proper hole for in the bone for the Fastener. 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 in both an open and arthroscopic version. Both sutured and sutureless versions will be marketed.

5. INTENDED USE:

The 3.5mm ROC XS Suture Bone Fastener is intended for use in bladder neck suspension for female urinary incontinence due to urethral hypermobility.

6. COMPARISON OF CHARACTERISTICS:

7.

The Innovasive Devices Rotator Cuff Fastener is comprised of acetal plastic. This device is used to secure suture in a predrilled hole in bone. It remains fixed in the bone through the spreading of the fingers of a crown component resulting in an inverted umbrella design.

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.

7. PERFORMANCE DATA:

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

1. Bone model testing: Comparison of the ultimate holding strength and the strength with #2 suture in a bone model compared to the predicate device. The Innovasive 3.5mm ROC XS suture bone fastener holding strength was found to be equivalent to the strength of the predicate device.