PARCUS MEDICAL, LLC.

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510(k) Summary

510(k) Owner:	Parcus Medical, LLC 6423 Parkland Dr Sarasota, FL 34243
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Device Trade Name:	Anatomic Thumb Ligament Arthroplasty System (ATLAS)
Common Name:	Thumb Joint Repair System
Device Class:	Class II
Classification Name:	Fastener, Fixation, Non-Degradable, Soft Tissue 21 CFR 888.3040 - Product Code MBI

Predicate Device:	K122805 – Draw Tight Anchors, cleared 2/5/13 K152711 – GFS Naked, cleared 12/10/15

Device Description:

The Parcus ATLAS is designed for use in CMC arthroplasty. The ATLAS is comprised of medical grade titanium, PEEK-OPTIMA™ from Invibio™, and UHMWPE. The ATLAS is provided sterile.

Intended Use:

The Parcus ATLAS is indicated for use in CMC arthroplasty.

Substantial Equivalence Summary:

The Parcus ATLAS is a combination of two different cleared Parcus Medical devices that can be used together in order to complete an anatomic CMC arthroplasty. This is achieved by inserting the Draw Tight Suture Anchor into the 2nd metacarpal and then using the tails of the suture anchor and a GFS Naked to secure the 1st metacarpal. The materials, manufacturing processes, packaging, sterilization and shelf-life of this device were considered and found to all be nearly identical to that of the predicate devices. The sterilization validation and shelf life study that were previously conducted were determined to be sufficient and therefore no additional testing was deemed necessary. From a performance aspect, the use of the ATLAS components is nearly identical to that of the original device's cleared indications and any differences have been determined to be insignificant. LAL testing has been conducted on each component individually and it was concluded that even when assembled together, the ATLAS does not raise any additional concerns regarding pyrogenicity.

Summary Performance Data:

The Parcus ATLAS was evaluated in order to ensure that all worst case conditions were considered. The individual performance of the components of this device was evaluated using cyclic loading and straight tensile loading. The ultimate strength and elongation of the construct were considered and the ATLAS was determined to be safe and effective for use in CMC arthroplasty. The performance of the ATLAS as a system is determined to be substantially equivalent to that of the predicate component devices.