

510(k) SUMMARY

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Submitter's Name: Avanta Orthopaedics
9369 Carroll Park Drive, Suite A
San Diego, CA 92121
619-452-8580

Contact: Louise Focht
Date of Preparation: November 1, 1996
Device Name: Avanta Orthopaedics Trapezial Implant
Common Name: Trapezial Implant
Predicate Device: Dow Corning Corporation Silastic H.P.
Trapezial Implant

Device Description:

The Avanta Orthopaedics Trapezial Implant is a device intended to be implanted in the trapezial bone of the wrist. It is made of molded silicone elastomer. The device is intended to be used in the treatment of thumb disabilities because of osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis as follows: Localized pain and palpable crepitation during circumduction movements with axial compression of the thumb. Loss of thumb motion with decrease of normal pinch and grip strength. Radiological evidence of arthritic changes of the trapeziometacarpal joint of the thumb or thumb and index finger in combination. Unstable, stiff, or painful distal joints of the thumb or swan-neck deformity.