

K964359

MAR 25 1997

510(k) SUMMARY

Submitter's Name:	Avanta Orthopaedics 9369 Carroll Park Drive, Suite A San Diego, CA 92121 619-452-8580
Contact:	Louise Focht
Date of Preparation:	September 24, 1996
Device Name:	Avanta Orthopaedics Tendon Spacer
Common Name:	Tendon Spacer
Predicate Device:	Wright Silastic Tendon Spacer

Device Description:

The Avanta Orthopaedics Tendon Spacer is a device intended to be implanted made of silicone elastomer which is reinforced with dacron polyester mesh and suture. The device is intended to be used in the surgical reconstruction of a flexor or extensor tendon of the hand. The device may be implanted long enough to permit maturation of the tendon bed to the point at which it can nourish and lubricate the gliding tendon graft. The device may be implanted for a period of time from 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon or to function as a scaffold for soft tissue ingrowth.

The tendon spacer will be available in four sizes, 3,4,5 and 6 mm diameter and 24 cm in length:

Device Intended Use:

Surgical indications for the Avanta Orthopaedics Tendon Spacer include: Reconstruction of the flexor or extensor tendons of the fingers, thumb and wrist. Scarred or adherent tendons following trauma or failed primary repair. Absence of tendon sheath. Scarred or adherent non-functional tendon pulleys. Ruptured tendon. The device is a single-use, temporary implantation for 2-6 months.