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K963302

Section XI - Summary of Safety and Effectiveness

Date of Preparation: August 16, 1996

Device Name: Tayman Medical, Inc. Stepping and Stabilization System

Classification Name: Guide Surgical Instrument 79FZX

Manufacturer: Tayman Medical, Inc. located at 15 Foxhunt Drive, Chesterfield, Missouri 63017

Predicate Device: The Tayman Medical, Inc. Seeding Device is substantially equivalent in intended use, safety and effectiveness and construction to the Teknar, Inc. Seeding device. That device was produced and marketed by Teknar, Inc. formally located at 267 Wolfner Drive, Fenton, Missouri 63026.

Device Description: The seeding device is comprised of three basic components. The adjustable height base. The adjustable, multi-axis head. The ultrasound probe holder and needle guide.

Intended Use: The Tayman Medical, Inc. Stepping and Stabilization System is used to provide precision ultrasound probe alignment and radioactive seed implantation in the treatment of prostate cancer.

Clinical and Non-Clinical Similarities and Differences: The Tayman Medical, Inc. Stepping and Stabilization System is substantially equivalent to the Teknar, Inc. Seeding device since they both are used to provide precision ultrasound probe alignment and radioactive seed implantation in the treatment of prostate cancer. They are operated in the exact same way and are made from the same materials.