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510(k) Summary for
LAGUNA™ Softip® diagnostic catheter

K 961499

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Trade/Proprietary Name: LAGUNA™ Softip® diagnostic catheter

Classification: Class II

Equivalent Devices Softip® High Flow diagnostic catheter (5 FR, 7 FR)
INFINITI™ diagnostic catheter (5 FR)
SUPER TORQUEPLUS™ diagnostic catheter (7 FR)
GUIDEZILLA™ Softip® guiding catheters (packaging & sterilization)

Device Description

The LAGUNA™ diagnostic catheter is manufactured in three French sizes (5 FR, 6 FR and 7 FR) and multiple distal stem configurations and lengths. In addition, within each French size, catheters will be offered with differing handling characteristics to allow flexibility in meeting physician preferences.

Intended Use

The LAGUNA™ Softip® diagnostic catheter is designed for delivering radiopaque media to selected sites in the vascular system.

Technological Characteristics

The following tests were performed on the LAGUNA™ Softip® diagnostic catheters and approved predicate device to show equivalence: bond strength tests, flexural rigidity, bodystock force delay, tip shape recovery, flow rate, pressure injection/leak test, output torque, input torque to failure and distal pressure testing.

The results of these tests indicate that the LAGUNA™ Softip® diagnostic catheters are equivalent to the previously approved predicate device and is therefore safe for its intended use.