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XVI. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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Device Description

The FTCM System combines well-established procedures of HSG, co-axial catheterization and microendoscopy. The FTCM System is composed of the following components: Soft Seal Cervical Catheter, Soft Torque Uterine Catheter and Accessory Valve, and/or Articulating Tip Hysteroscope, Variable Softness Catheter, guidewires: the Robust Guidewire, the Traveler Guidewire, the Supple Guidewire and the Pirouette Guidewire, and a Microendoscope with Eyepiece. Each component is described below;

a. Soft Seal Cervical Catheter

The Soft Seal Cervical Catheter is a dual lumen device with a latex balloon located at the distal end. The Cervical Catheter is packaged with a malleable Obturator which can be shaped with a gentle curve and will increase column strength of the catheter when inserted completely into the Cervical Catheter. The proximal end of the Cervical Catheter has two ports, one to inflate the balloon and one to access the through-lumen. A two-way stopcock on the balloon port maintains inflation during use. The through-lumen allows injection of dye, contrast medium, or sperm into the uterus and/or serves as a conduit for the Obturator and/or Conceptus Uterine Catheter.

b. Soft Torque Uterine Catheter, Mandrel and Accessory Valve

The Soft Torque Catheter serves as a conduit to the proximal portion of the fallopian tube for the Conceptus Variable Softness Catheter, Guidewire and Microendoscope. The Soft Torque Catheter is a single lumen device with a curved distal tip. The Catheter is packaged with a Mandrel which will straighten the tip curve when inserted completely into the catheter. The hub located at the proximal end of the Catheter has two ports. The side port is used for the attachment of a syringe for injection and is in the same plane and direction as the tip curve. The end port is used for introduction of the Mandrel and / or Variable Softness Catheter and has a valve to prevent reflux during injection. The Soft Torque Catheter can access the utero-tubal ostium through a rigid hysteroscope with direct visualization.

c. Articulating Tip Hysteroscope

The Articulating Tip Hysteroscope is used to permit direct viewing of the cervical canal, the uterine cavity and utero-tubal ostium by a telescopic system introduced into the uterus through the cervix. The scope has a rigid shaft with a flexible articulating tip. The device is

equipped with a separate eyepiece plug and light guide plug. The optical system conveys an image to the user's eye or to a video camera.

d. Variable Softness Catheter

The Variable Softness Catheter is an over-the-wire catheter which is intended to access the proximal portion of the fallopian tube. The catheter is used through the Conceptus Soft Torque Uterine Catheter or Articulating Tip Hysteroscope. It is a single lumen 3 French (1 mm) catheter with graded shaft flexibility. The hub located at the proximal end of the catheter has two ports. The side port is used for the attachment of an irrigation tube or a syringe for injection. The endport is used for introduction of the guidewire and microendoscope and has a valve to prevent reflux during injection of dye and/or irrigation fluid. The catheter has a proximal marker which indicates when the Conceptus Variable Softness Catheter is about to exit the Conceptus Soft Torque Catheter.

e. Guidewire

The Conceptus Guidewires are intended for use to increase column strength of the Variable Softness Catheter during positioning within the proximal portion of the fallopian tube. The guidewires have a tapered core wire and a distal coil section for flexibility, and a proximal handle to lock the guidewire into position with the Variable Softness Catheter. The two models differ only with respect to the wire diameter profile and the mid-to-distal coil length. This difference in taper and coil lengths imparts varying degrees of flexibility to the guidewire, and guidewire selection will be based on physician preference.

f. Microendoscope

The Conceptus Microendoscope is an ultra-thin, flexible fiberscope designed for use with the Conceptus Variable Softness Catheter. It is to be used with a Conceptus Eyepiece which is detachable and has adjustable focus. The microendoscope is equipped with a separate image plug and light plug. The light plug has an ACMI-type male connector. The length of the cable provides easy handling when imaging on a television monitor.

g. Eyepiece

The Conceptus detachable Eyepiece is designed to fit onto the image plugs of the Conceptus Microendoscope. The Eyepiece has an adjustable focus and an alignment marker on its tip. The cleaning plug should always be inserted for cleaning and storage.

Indications for Use

The Conceptus FTCM System is intended for use in selective catheterization/cannulation of the fallopian tubes in order to evaluate proximal tubal occlusion or patency under direct visualization.

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Substantial Equivalence

The Conceptus FTCM System is substantially equivalent to the Conceptus FTC System. Comparative performance testing demonstrated that the Conceptus FTCM System is substantially equivalent to the Conceptus FTC System with respect to force required to navigate the fallopian tube model. Additionally, performance testing and clinical data were provided for the Conceptus FTCM System which further substantiated equivalence.