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# Conceptus

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## **Conceptus Hysteroscope Summary of Safety and Effectiveness**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The Conceptus hysteroscope is used to permit direct viewing of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix for both diagnostic and operative procedures.

The Conceptus hysteroscope 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.

The intended use, optics, design, materials, specifications and mode of operation of the Conceptus Hysteroscope were found to be substantially equivalent to several predicate hysteroscopes.

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