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510(k) Summary

A. REQUIRED INFORMATION

1. Submitted by  
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2. Device name  
Tampa Hysterosonography Set
3. Predicate Devices
  - a. Ackrad Intrauterine Insemination Set, K940176/A
  - b. "Goldstein" Sonohysterography Catheter.
4. Description of the device (see exhibit 2)

The Tampa Hysterosonography set will consist of two parts:  
a single lumen catheter and a semi-rigid introducing  
sheath.

The catheter will be available in a 5-French diameter with  
a length of 33 cm. The distal end will have either a side  
port or end port. The proximal end will be fitted with a  
female luer-lock hub. The catheter will be banded with  
non-toxic ink 7 cm. from the distal tip.

The semi-rigid sheath has an internal diameter to allow  
easy movement over the catheter and a wall thickness  
sufficient to provide semi-rigid flexibility. It is 16  
cm. long, and flanged and rounded at the distal end to  
provide a non-traumatic surface to the tissues. The  
proximal end allows for temporary fixation over the  
proximal hub of the catheter.

5. Indication for use

Injection of saline in the examination of the uterus using  
ultrasound techniques.

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## 6. Technical Characteristics

The materials and construction of the Tampa Hysterosonography Set are identical to those of the approved predicate device, K940176/A with the exception of the lengths of the catheter and placement sheath.

### B. PERFORMANCE DATA

1. Non-clinical tests  
Not applicable
2. Clinical results  
Procedures for hysterosonography using the predicate IUI Set demonstrate the safety and effectiveness of that product for hysterosonography. (See exhibits 5A and 5B)
3. Biocompatibility  
Equivalent to the predicate IUI Set , as material and location of use are identical.

### C. CONCLUSION OF SAFETY AND EFFECTIVENESS

The above description, indications for use, technological characteristics, and clinical results demonstrate that the Tampa Hysterosonography Set is substantially equivalent in safety and effectiveness to the predicate devices, the Ackrad IUI Catheter Set, K940176/A and the Goldstein Sonohysterography Catheter.