Section 4. 510(k) Summary

APR 30 2008

General Provisions

Submitter's Name and Address:	EKOS Corporation 11911 North Creek Parkway South Bothell, WA 98011
Contact Person:	Jocelyn Kersten 425-415-3132 425-415-3102 (fax) jkersten@EKOSCORP.com
Classification Name:	Catheter, Continuous Flush (KRA)
Regulation Number:	21 CFR §870.1210
Common or Usual Name:	Continuous Flush Catheter
Proprietary Name:	EndoWave Infusion System
Name of Predicate Device:	EndoWave Infusion System
510(k) Reference No.:	K072507, K062508

Device Description
The system consists of a disposable infusion catheter with removable ultrasound core and an instrument that generates and controls the delivery of energy to the catheter. The infusion catheter contains multiple side holes distributed over the length of the treatment zone. The ultrasound core contains up to 30 ultrasound elements, evenly spaced over the treatment zone. Thermal sensors in the treatment zone monitor catheter temperature.

Intended Use
The EndoWave Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Summary of Technological Characteristics
The device modification described in this notification does not affect the technological characteristics for the EndoWave Infusion System.

Test Summary
Testing confirmed the revised acoustic protocol remains safe and the ultrasound core will operate as required with the new protocol.