

K960415

APR 26 1996

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK BALLOON INFLATION DEVICE

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:

The Wilson-Cook Balloon Inflation Device is a hand-held mechanical device consisting of a 20cc capacity syringe, a 300 psi/20atm pressure gauge, a plunger mechanism, lever, extension line, and stopcock. This device is to be used to inflate, deflate and monitor pressure for gastrointestinal dilation balloons.

Classification Name: Syringe, Balloon Inflation, 74 MAV

Classification: FDA has classified similar devices as Class II. This device falls within the purview of the Gastroenterology and Urology Devices Panel.

Trade/Proprietary Name: Wilson-Cook Dilation Balloon Inflation Device.

Common/Usual Name: Balloon Inflation Device

Performance Standards: To the best of our knowledge, performance standard for this device do not exist.

Sterility: Validated EO cycle following AAMI Overkill Method to SAL 10^{-6} .

Intended Use: This device is a disposable device to be used to inflate, deflate and monitor pressure for gastrointestinal dilation balloons.

Predicate Devices: This device is similar with respect to technological characteristics and intended use to predicate balloon inflation devices, including the Microvasive Digiflator™ (K860589) and the Wilson-Cook Balloon Inflation Device (K936168).

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK BALLOON INFLATION DEVICE

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

CHARACTERISTIC	Wilson-Cook Balloon Inflation Device [Subject of 510(K)]	Microvasive Digiflator™ (K860589)	Wilson-Cook Quantum Inflation Device (K936168)
Intended Use	Used to inflate, deflate and monitor pressure of the Wilson-Cook line of balloon dilators for GI use.	Used to inflate, deflate and monitor pressure of balloon dilators for GI use.	Used to inflate, deflate and monitor pressure of the Wilson-Cook line of balloon dilators for GI use.
Construction	Plunger mechanism to control pressure.	Plunger mechanism to control pressure.	Plunger mechanism to control pressure.
	20 cc syringe	60 cc syringe	60 cc syringe
	Hand held design.	Hand held design.	Hand held design.
	Extension line with stopcock for connection to balloon.	Extension line for connection to balloon.	Extension line for connection to balloon.
	Analog pressure gauge	Digital pressure gauge	Analog pressure gauge
Sterility	Sterile and non-sterile.	Available sterile and non-sterile.	Non-sterile.
	Disposable	Disposable	Disposable

Testing: The Wilson-Cook Balloon Inflation device has been subjected to in-house functional testing to demonstrate device integrity. All samples tested were deemed acceptable in that testing specifications were met.