

MAY - 1 1996

**Martech Endoscopic Injection Needle
510(k) Summary**

Predicate Devices: Bard Endoscopic Injection Needle (K933812) and Mill-Rose Endoscopic Injection Needle (K820973)

Intended Use of the Device:

The Martech Endoscopic Injection Needle is indicated for use as an accessory for currently marketed endoscopes to provide for delivery of injectable materials into tissues during endoscopic procedures.

As with currently marketed endoscopic injection needles, the Martech Endoscopic Injection Needle may be used in a variety of endoscopic procedures for the delivery of a variety of injectable materials which have received approval for use by the FDA. The type of material to be injected will be dependent on the nature of the endoscopic procedure, but such materials may include for example: delivery of collagen during cystoscopic procedures; delivery of sclerosing agents during esophagoscopic and gastroscopic procedures; delivery of local anesthetics during cystoscopic or laryngoscopic procedures; or delivery of saline or contrast media during colonoscopic procedures.

Device Description:

The Martech Endoscopic Injection Needle fits within various endoscopes with working channels having a 5 French or larger inner diameter and extends beyond the proximal end of the endoscope. The Endoscopic Injection Needle is sterile, disposable and nonpyrogenic. It consists of a non-coring, 23 gauge stainless steel needle attached to a flexible, 5 French polycarbonate catheter with luer lock hub. The luer lock hubs are designed to meet the "American National Standard for Medical Material, Luer Taper Fittings and Performance" (ANSI/HIMA MD70.1-1983). Moreover, these luer lock hubs are designed to accommodate standard syringes. To allow for smooth passage of the device through the endoscope's instrument channel, the transition between the needle and catheter assembly is tapered.

The Endoscopic Injection Needle will be provided in a variety of lengths, up to 200 cm, in order to accommodate for different length instrument channels. The needle length will be specified on the device's unit label. In general, the shorter needles will be used with shorter endoscopes such as bronchoscopes and the longer needles may be used with longer endoscopes such as flexible gastroscopes and colonoscopes.