

K962736
JUL 29 1996

510(k) Summary:

- 1.) Submitter: Mill-Rose Laboratories, Inc.
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- 2.) Contact Person: Alan C. Poje
- 3.) Summary Preparation Date:
July 12, 1996
- 4.) Classification Name: Bronchoscope and Accessory
- 5.) Common Name: Laryngoscopic Injection Needle
- 6.) Proprietary Name: Mill-Rose Laryngoscopic Injection Needle
- 7.) Substantially Equivalent Devices:
K914181: Wang/Mill-Rose Transbronchial Aspiration Needle
K820973: Endoscopic Injection Needle
- 8.) Description of Subject Device:
The device consists of an outer catheter and an inner catheter to which a needle is mounted. The inner catheter slides within the outer catheter such that the needle tip may advance a pre-determined distance past the end of the outer catheter and remains totally within the lumen catheter when the needle is fully retracted.
- 9.) Intended Use:
The device is intended to be used through a laryngoscope for the therapeutic injection the larynx for various laryngeal disorders such as paralysis, tissue deficiency, contact ulcers and spasmodic dysphonia.
- 10.) Technological Characteristics:
The subject device has the same technological characteristics as its predicate devices. It is composed of the same type of materials and is of a similar design.