

K960880

510(k) Summary:

1.) Submitter: Mill-Rose Laboratories, Inc.
7310 Corporate Blvd.
Mentor, OH 44060
(216)255-7995

APR 29 1996

2.) Contact Person: Alan C. Poje

3.) Summary
Preparation Date: February 29, 1996

4.) Classification Name: Not Known

5.) Common Name: Blind Protected Specimen Brush

6.) Proprietary Name: Mill-Rose Blind Microbiology Brush

7.) Substantially Equivalent Device:
K820771 - Mill-Rose Laboratories, Inc., Microbiology Brush

K923487 - Ballard Medical Products, BAL Cath®

8.) Description of Subject Device:

The subject device is sterile and consists of a flexible polymeric inner sheath which is contained within an outer sheath. Within the inner sheath is a twisted wire brush. The outer sheath is occluded with a polyethylene glycol wax plug. Upon use, the inner sheath is advanced, the plug expelled and the brush advanced to provide a sterile, non-contaminated specimen brush.

9.) Intended Use:

The device is intended to allow blind, non-directed, protected specimen brush sampling of the lower respiratory tract secretions or to perform surveillance cultures or to diagnose pneumonia in patients receiving mechanical ventilation.

10.) Technological Characteristics:

The subject device combines technological characteristics of both predicate devices. It is composed of the same type of materials and is of a similar design.

) I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

We would appreciate your earliest attention to this submission. Please contact me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan C. Poje', written in a cursive style.

Alan C. Poje
Director of Regulatory Affairs

ACP/ap

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