



HARDWOOD PRODUCTS COMPANY

GUILFORD, MAINE 04443-0149 U.S.A.

TELEPHONE (207) 876-3311 · 1-800-321-2313
FAX: (207) 876-3130 · 1-800-323-4153

K961934

JUL 9 1996

APPENDIX III

510(k) Summary of Safety and Effectiveness

This Summary of is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 870.92

1. Submitted by : Hardwood Products Co.
P.O. Box 149, School St.
Guilford, Me 0443-0149
2. Contact Person: William M. Young, QC Manager
207-876-3311
Fax 207-876-3130
3. Trade Name : Puritan Foam Tip Swab
Common Name: Foam tip swab/applicator
Classification Name: Cervical cytological spatula
4. Predicate Devices: Absorbent Tip Applicator (Hardwood Products Co. K902338)

Cell Collecting Brush (Anderson Winn Paper Co. K924908)
5. Device Description: The Puritan Foam Tip Swab consists of a polyurethane foam tip bonded to a high impact polystyrene shaft with hot melt adhesive. The device is for single use only and non-sterile.
6. Intended Use: The Puritan Foam Tip Swab is used to obtain a Pap smear sample from the endocervix.
7. Device Comparison: The Puritan Foam Tip Swab is similar to the cell collecting brush for materials, construction, and dimensions.
8. Non-clinical tests: Polyurethane foam has been shown to be biocompatible. Test reports are attached and available in Device Master File, MAF#139. Tip adhesion testing has shown the Puritan Foam Tip Swab comparable to the Cell Collecting Brush.
9. Functional Clinical Performance: A study of Pap smears from each device showed the Puritan Foam Tip Swab to be as effective as the Cell Collecting Brush for obtaining and transferring to a slide cervical cytological specimens that are adequate for diagnosis.

*Discipline: Swab
This is a foam swab
for K961934
Approved
Date: 7/9/96*