

K954710

CONFIDENTIAL

EXHIBIT #9a

SUMMARY OF SAFETY AND EFFECTIVENESS

K954710

Common/Usual Name: Resectoscope Electrodes

APR 24 1996

Proprietary Name: Vapor-Tech Roller, Vapor-Tech Grooved Roller,
Vapor-Tech Ball, Vapor-Tech Scoop

Classification: CLASS II

Materials:

All materials used to manufacture the Northgate Technologies Inc. Electrodes are non-toxic and have been previously used to manufacture other medical devices.

Description:

Northgate's Cutting Loops and Knife Resectoscope Electrodes are designed to be used with most major brands of Resectoscopes. The electrodes are used to cut and coagulate soft tissue during electrosurgical procedures.

The Vapor-Tech Series Electrodes are designed with several tip configurations: roller, grooved roller, ball, and scoop.

Substantial Equivalence:

Northgate's Resectoscope Electrodes are substantially equivalent in design, materials, and intended use to numerous currently marketed devices. Other manufacturers of similar devices are Circon/ACMI, Olympus, Storz Products, Inc., and Richard Wolf.

Intended Use:

Northgate Technologies Inc. Resectoscope Electrodes are intended to be used in urological procedures.