

EXHIBIT X

K960232

510(k) SUMMARY

MAR 21 1996

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Director of Regulatory Affairs

January 15, 1996

Trade Name: Endoscopic Access Device
Common Name: Endoscopic Access Device
Classification name: Not Known

The Endoscopic Access Device is an instrument access portal for use during endoscopic surgery. It is designed to be substantially equivalent to the presently marketed AMT Esophageal Overtube. The devices' internal flange is inserted into the incision site and allowed to expand freely. Once in place, the internal flange retains the device in place and allows for the access of a variety of surgical instruments.

The shaft is angulated at 30° but can range from 20° to 90°, depending on the specific application. The external flange reduces site contamination and trauma. It also easily defines the access into the region.

The Endoscopic Access Device is injection molded from the same biocompatible Dow Corning silicone (Q7-4840) as the AMT Button (K943392). The Endoscopic Access Device has been developed incorporating all of the safety and effectiveness features for this devices' application. Bench testing and has been performed on the minimum pull out force versus the the strength of the device to ensure mechanical integrity for functional performance (see Exhibit VIa).

The Endoscopic Access Deivce is sold sterile for single use.