

## XIII.

## 510 (k) Summary for 5 Star Medical, Inc.

MAY - 8 1996

DEVICE NAME

Bronchoscope

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Microvasive Visicath

DESCRIPTION OF DEVICE

A description of the Bronchoscope's components is as follows:

Optical Catheters

The deflecting tip optical catheters are available in various lengths (30 to 100 cm) and outer diameters (1.6 to 2.7 mm) for visualization of the trachea and lungs. They are available with a working channel, fiber optic cable connection and device for deflection. Manipulation at the proximal end of the flexible scope activates the deflection of the distal tip.

Optical Handle

The optical handle consists of an eye piece, a barrel and an optical connection. The handle incorporates magnifying optics which can be adjusted for focus with the focusing ring.

Fiber Optic Cables, Adapters and Light Sources

The fiber optic cables consist of a bundle of non-coherent glass fibers. The fiber optic bundle is sheathed. The light source end of the cable is configured to fit various light sources currently available in distribution (e.g. Wolf, Olympus, Storz and ACMI). The instrument end of the cable is finished with a female ACMI type connector. Light sources which are in common use are compatible with the Bronchoscope. Diagnostic and photo light sources are effective and safe to use with this system. The adapters which are included with the fiber optic cable provide for connection to light sources built by Wolf, Olympus, Storz and ACMI.

### STATEMENT OF INTENDED USE

The 5 Star Medical bronchoscope is intended for use in the direct visualization and diagnosis in the trachea and lungs.

### STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Microvasive Visicath is intended for use in the direct visualization and diagnosis in the trachea and lungs.

### STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

The 5 Star Medical Bronchoscope has substantially equivalent technological characteristics compared to the predicate Microvasive Visicath device. The devices' field of view, focusing capability, focal lengths, design configuration (i.e. the body, working channels and imaging/light fiber configuration) are similar and comparable. The biocompatibility of the materials of both devices are similar and comparable. In addition, the mode of operation of both devices are similar and comparable.

### DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The 5 Star Medical Bronchoscope is substantially equivalent to the Microvasive Visicath. Both devices are intended for direct visualization and diagnosis of the trachea and lungs. The technological characteristics of the Bronchoscope and predicate device (design, materials, and mode of operation) are comparable and determined to be substantially equivalent.