APR - 4 1996

K960089

510(k) SUMMARY
ProChek® G Glutaraldehyde Concentration Level Indicator
January 4, 1996

K960089

1. SUBMITTER NAME AND ADDRESS

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1.1 Submitter

Cottrell, Ltd.
7399 South Tucson Way
Englewood, CO 80112
Telephone # (800) THE-EDGE
Telefax # (303) 799-9408
John Scoville, Director of Regulatory Affairs and Quality Assurance

2. DEVICE NAME

Proprietary Name:	ProChek® G Glutaraldehyde Concentration Level Indicator
Common/Usual Name:	Glutaraldehyde Concentration Indicator
Classification Name:	Sterilization Process Indicator; Physical/Chemical Process Indicator

3. PREDICATE DEVICES

Albert Browne Ltd., GA Glutaraldehyde Concentration Monitor
Pymah Corporation Cold Sterilog Glutaraldehyde Monitor

4. INTENDED USE

The Cottrell, Ltd., ProChek® G Glutaraldehyde Concentration Level Indicator is a 1.5% minimum effective concentration (MEC) monitor intended for use in 2-3.5% activated glutaraldehyde solutions.

5. DEVICE DESCRIPTION

The ProChek® G Glutaraldehyde Concentration Level Indicator is a chemical indicator strip with a minimum effective concentration of 1.5% glutaraldehyde designed to monitor

solutions, containing up to 3.5% activated glutaraldehyde. The indicator pad changes from yellow to purple, indicating a pass, if the active glutaraldehyde concentration in the solution being tested is greater than or equal to 1.75%.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Cottrell, Ltd. ProChek® G Glutaraldehyde Concentration Level Indicator are identical to those of the Albert Browne Ltd. GA Concentration Monitor. The proposed device is the same indicator, purchased in bulk from the manufacturer, and packaged and labeled by Cottrell, Ltd.

7. TESTING

This testing was performed to evaluate the permeability of the moisture proof containers used for shipping the ProChek® G Glutaraldehyde Concentration Level Indicator from Albert Browne Ltd. to Cottrell, Ltd. for packaging and labeling.

To test the permeability of the shipping containers, containers were filled with silica gel bags and sealed. The weight of each container was recorded immediately after sealing. After twelve hours, in a controlled environment of 65% humidity at 40°C, the containers were weighed and compared with the weights obtained at the time of sealing. None of the experimental containers used for shipping gained weight.

Testing demonstrates that the packaging modification does not impact the safety or effectiveness of the device.