K063285

JAN 12 2007

# APPENDIX F

## 510(k) Summary for Reliance™ CI Process Indicator

# 510(k) Summary
# for
# Reliance™ CI Process Indicator

## 1. SUBMITTER NAME AND ADDRESS

Richard Bancroft
Albert Browne Ltd., a Subsidiary of STERIS Corporation
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Contact: Richard Bancroft
Telephone number: 44 116 276 8636

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Reliance™ CI Process Indicator |
| Common/Usual Name: | Chemical indicator |
| Classification Name: | Physical/chemical sterilization process indicator |

## 3. PREDICATE DEVICE

- Reliance™ PI Process Indicator (K043482)

## 4. INTENDED USE

The Reliance™ CI Process Indicator is intended for routine monitoring of the Reliance™ EPS Endoscope Processing System employing Reliance™ DG Dry Germicide. The Reliance™ CI Process Indicator is a peracetic acid dose indicator that changes color from orange to white (colorless) upon exposure to an effective dose of peracetic acid.

## 5. DEVICE DESCRIPTION

The Reliance CI is a single-use chemical indicator with indicator ink printed on one end that was developed to monitor the peracetic acid (PAA) dose at the point of use in a Reliance™ EPS Endoscope Processing System employing Reliance™

DG Dry Germicide. The Reliance CI shows an incomplete color change when exposed to peracetic acid at a dose of 9,000 mg/L PAA min. in a Reliance™ EPS Endoscope Processing System cycle. The Reliance CI changes color from orange to white (colorless) when exposed to peracetic acid at a dose of 11,500 mg/L PAA min. in a Reliance™ EPS Endoscope Processing System cycle.

## 6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the proposed Reliance CI described in this submission are similar to the predicate Reliance™ PI Process Indicator. Both the Reliance CI and the Reliance™ PI Process Indicator are non-sterile, disposable polymeric strips with indicator ink that changes color in a Reliance™ EPS Endoscope Processing System cycle employing Reliance™ DG Dry Germicide. A table that compares the technological characteristics of the proposed and predicate devices is provided on the following page.

## 7. PERFORMANCE TESTING

Performance testing was conducted to demonstrate that the Reliance CI is an effective monitor for the circulating peracetic acid dose of the Reliance™ EPS Endoscope Processing System employing Reliance™ DG Dry Germicide.

**Comparison of Technological Characteristics**

| Characteristics | Reliance™ CI Process Indicator (proposed) | Reliance™ PI Process Indicator (STERIS Corporation, K043482) |
|---|---|---|
| Material – Indicator | printed indicator ink overlaid with a clear, permeable laminate | Cellulose paper pad impregnated with reagents |
| Material – Indicator Substrate | polypropylene | polystyrene |
| Disposable | yes | yes |
| Active Component Monitored | peracetic acid dose | peracetic acid dose |
| Color Change | orange to white | purple to pale grey or lighter |
| Response to Peracetic Acid Dose | | |
| Colorless[1] | ≥11,500 mg/L PAA min. | ≥11,500 mg/L PAA min. |
| Incomplete color change[2] | ≤ 9000 mg/L PAA min | ≤ 9000 mg/L PAA min. |
| Orange | Unprocessed | Unprocessed |

[1] The endpoint color is actually the absence of color, which appears white (the color of the strip on which the indicator ink is printed)

[2] Any shade of orange or any color other than the reference pass color

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Albert Browne Limited
C/O Cynthia J. M. Nolte, Ph.D., RAC
Senior Regulatory Consultant
Medical Service Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

JAN 12 2007

Re: K063285
Trade/Device Name: Reliance™ CI Process Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: December 22, 2006
Received: December 26, 2006

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

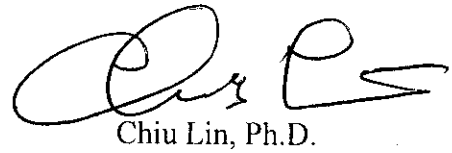
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K06 3285

Device Name: Reliance™ CI Process Indicator

Indications For Use:

The Reliance™ CI Process Indicator is intended for routine monitoring of the Reliance™ EPS Endoscope Processing System employing Reliance™ DG Dry Germicide. The Reliance™ CI Process Indicator is a peracetic acid dose indicator that changes color from orange to white (colorless) upon exposure to an effective dose of peracetic acid.

Prescription Use _____ AND/OR Over-The-Counter Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila N. Murphy M.D.
Radiological Technology, General Hospital
Infection Control, Dental Devices
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