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SECTION 2. SUMMARY AND CERTIFICATION

2.A. 510(k) Summary

Submitter:	SterilMed, Inc.
Contact Person:	Dr. Bruce Lester SterilMed, Inc. 11400 73rd Avenue North Minneapolis, MN 55369 Ph: 763-488-3400 Fax: 763-488-3350
Date Prepared:	September 26, 2004
Trade Name:	Reprocessed Cold Biopsy Forceps
Classification Name: and Number:	Gastroenterology-Urology Biopsy Instruments Class I, 21 CFR 876.1075
Product Code:	NON
Predicate Device(s):	The reprocessed cold biopsy forceps are substantially equivalent to the Precisor EXL Cold biopsy Forceps manufactured by Bard and the Radial Jaw 3 Cold biopsy forceps manufactured by Microvasive. Both of the predicate devices are Class 1 devices.
Device Description:	The device consists of a proximal handle which is connected, via a coil, spring or rod mechanism, to the biopsy jaws at the distal tip. The biopsy forceps range from 100 to 240cm in length and 1.8-3.3mm in diameter. The jaws range from 1.8 to 3.3mm in diameter. The jaws of the forceps may or may not have serrated edges, a fenestration, needle, or distal biting tooth.

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Intended Use:	The Reprocessed Cold Biopsy Forceps are intended to be used during endoscopic procedures of the gastrointestinal tract to collect tissue samples for histologic examination. These forceps are advanced to the site for sampling via the operating channel of an endoscope.
Functional and Safety Testing:	Representative samples of reprocessed cold biopsy forceps underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.
Conclusion:	The cold biopsy forceps reprocessed by SterilMed are substantially equivalent to their counterparts from the original manufacturers and to the Precisor EXL Cold Biopsy Forceps manufactured by Bard and the Radial Jaw 3 Cold biopsy forceps manufactured by Microvasive. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2005

Bruce R. Lester, Ph.D.
Vice President of R&D
SterilMed, Inc.
11400 73rd Avenue, North
MINNEAPOLIS MN 55369

Re: K042648
Trade/Device Name: SterilMed Reprocessed Cold Biopsy Forceps (see enclosure)
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: I
Product Code: NON
Dated: April 28, 2005
Received: April 29, 2005

Dear Dr. Lester:

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ENCLOSURE

Table 1 – BARD Cold Biopsy Forceps to be Reprocessed

Original Manufacturer (BARD) Manufacturer Number	Cup Type	Jaw Size (mm)	Length (cm)
000381	Alligator	2.3	160
000382	Alligator w/ Needle	2.3	160
000383	Oval	2.3	160
000384	Oval w/ Needle	2.3	160
000385	Alligator w/ Needle	2.3	230
000386	Alligator w/ Needle	2.3	230
000388	Oval w/ Needle	2.3	230
000389	Oval	2.3	230
00820C	Oval	3.1	230
00821C	Oval w/ Needle	3.1	230
00822C	Alligator	3.1	230
00823C	Alligator w/ Needle	3.1	230
100512	Oval	1.8	160
100513	Alligator	1.8	160
000837	Oval	2.3	160
000838	Oval w/ Needle	2.3	160
000840	Alligator	2.3	160
000841	Alligator w/ Needle	2.3	160
000816	Oval	2.3	230
000817	Oval w/ Needle	2.3	230
000818	Alligator	2.3	230
000819	Alligator w/ Needle	2.3	230
000820	Oval	3.1	230
000821	Oval w/ Needle	3.1	230
000822	Alligator	3.1	230
000823	Alligator w/ Needle	3.1	230
100516	Oval	1.8	160
100517	Alligator	1.8	160

Table 2 – Microvasive Cold Biopsy Forceps to be Reprocessed

Original Manufacturer (**Microvasive**) Manufacturer Number	Cup Type	Jaw Size (mm)	Length (cm)
1530	Alligator	2.2	100
1531	Alligator w/ Needle	2.2	100
1534	Alligator	2.2	160
1535	Alligator w/ Needle	2.2	160
1536	Alligator	2.2	240
1537	Alligator w/ Needle	2.2	240
1596	Large Capacity Alligator	2.2	160
1597	Large Capacity Alligator w/ Needle	2.2	160
1598	Large Capacity Alligator	2.2	240
1599	Large Capacity Alligator w/ Needle	2.2	240
1586	Max Capacity Alligator	3.3	160
1587	Max Capacity Alligator w/ Needle	3.3	160
1588	Max Capacity Alligator	3.3	240
1589	Max Capacity Alligator w/ Needle	3.3	240
1578	Alligator	1.8	160
1579	Alligator w/ Needle	1.8	160
1265	Alligator w/Needle	2.2	240
1260	Alligator	2.2	160
1263	Alligator w/ Needle	2.2	160
1271	Alligator	2.2	240
1584	Max Capacity Alligator	3.3	240
1585	Max Capacity Alligator w/ Needle	3.3	240
1274	Large Capacity Alligator w/ Needle	2.2	240
1281	Alligator	1.8	160
1286	Alligator w/ Needle	1.8	160
1010	Multiple Sample Alligator	2.4	160
1012	Multiple Sample Alligator	2.4	240
1268	Alligator w/ Needle	2.2	100

Table 3 – Wilson-Cook Cold Biopsy Forceps to be Reprocessed

Original Manufacturer (**Wilson-Cook**) Manufacturer Number	Cup Type	Jaw Size (mm)	Length (cm)
SDF -2.5 -160	Fenestrated	2.5	160
SDF -2.5 -160-S	Fenestrated w/ Needle	2.5	160
SDF -2.5 – 230	Fenestrated	2.5	230
SDF -2.5 – 230-S	Fenestrated w/ Needle	2.5	230

Indications for Use Page

Device Name: Reprocessed Cold Biopsy Forceps

Indications for Use: The Reprocessed Cold Biopsy Forceps are intended to be used during endoscopic procedures of the gastrointestinal tract to collect tissue samples for histologic examination. These forceps are advanced to the site for sampling via the operating channel of an endoscope.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042648

Prescription Use ✓
(Per 21 CFR 801.109)