SEP 2 2003

K032544

8 510 CUJ Summery/ Statement

I Submitter

MGB Endoskopische Geräte GmbH Berlin
Schwarzschildstraße 6
12489 Berlin
Germany

II Device Names

1.	Classification Name:	Accessory to an Endoscope
2.	Common or Usual Name:	Endoscopic camera
3.	Proprietary Name:	VP-1000C and VP-3000A for MGB brand, Med Cam 100 and Med Cam 300 for LAWTON brand

III Classification:

Class II. This device is described in21 C.F.R.§876.1500: The product code for the device is GCJ.

IV Predicate Device:

name/ manufacturer:	World of Medicine Lemke GmbH
labeling:	For VP-1000C (Med Cam 100): Endoscopic Camera MC404/C3 For VP-3000A (Med Cam 300): Endoscopic Camera MC804/C4

V Intended Use:

The Endoscopic cameras VP-1000C (Med Cam 100) and VP-3000A are intended to attach to standard endoscopes to permit visualization of body cavities, hollow organs and canals during endoscopic procedures. It also may be attached to a microscope. The endoscopic image can be displayed on any standard video monitor.

VI Device Describtion

The Endoscopic camera VP-1000C (Med Cam 100) is a 1-CCD camera, the VP-3000A (Med Cam 300) is a 3-Chip camera; both consist of a camera control unit (CCU), a camera head, various connecting objectives, cables and adapters. The Endoscopic cameras VP-1000C (Med Cam 100) and VP-3000A (Med Cam 300) take the image through standard endoscopes that would be normally seen with the naked eye, and displays it on any standard video monitor. The camera heads are supplied with an standard objective with the focal length 18, 25, 30 or 40mm. A Zoom objective can be used too. The devices allow focussing for both right-handed and left-handed users.

VII Substantial Equivalence

The submitted device pose the same type of questions about safety and effectiveness as the predicate device. The new device has no diminished safety or effectiveness.

The VP-1000C (Med Cam 100) is similar in design and technological characteristics to the Endoscopic camera MC404/C3 (K020336), the VP-3000A (Med Cam 300) is similar in design and technological characteristics to the Endoscopic camera TC804/C4 (K014158), manufactured by World of Medicine Lemke GmbH.

The Endoscopic camera VP-1000C (Med Cam 100), VP-3000A (Med Cam 300) and the predicate devices are all intended to permit visualization of body cavities, hollow organs and canals during endoscopic procedures. The camera head of the The Endoscopic camera VP-1000C (Med Cam 100), VP-3000A (Med Cam 300) and of the predicate devices is designed to attach to standard, commercially available, endoscopes and the endoscopic image in the proposed and predicate device can be displayed on any standard video monitor.

The differences between the VP-1000C (Med Cam 100), VP-3000A (Med Cam 300) and the predicate devices are minor and limited to picture quality and handling convenience. Accordingly, MGB Endoskopische Geraete GmbH Berlin believes that the Endoscopic cameras VP-1000C (Med Cam 100) and VP-3000A (Med Cam 300) are substantially equivalent to the predicate devices currently on the market.

VIII Performance Data

The Endoscopic Light source VP-1000C (Med Cam 100) and VP-3000A (Med Cam 300) will comply with the International Standard IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18 and will conform to the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2003

MBG Endoskopische Geräte GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K032544
Trade/Device Name: VP-1000C; Med Cam 100; VP-3000A; Med Cam 300
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FET
Dated: August 9, 2003
Received: August 18, 2003

Dear Mr. Preiss:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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

3 Statement of Indications for use

Applicant: MGB Endoskopische Geräte GmbH Berlin

510(k) Number: K032544

Device Name: Endoscopic Camera

i) VP-1000C (for MGB brand); Med Cam 100 (for Lawton brand)
ii) VP-3000A (for MGB brand); Med Cam 300 (for Lawton brand)

Intended Use of the Device

The Endoscopic cameras VP-1000C (Med Cam 100) and VP-3000A /Med Cam 300) are intended to attach to standard endoscopes to permit visualization of body cavities, hollow organs and canals during endoscopic procedures. It also may be attached to a microscope. The endoscopic image can be displayed on any standard video monitor.

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 C.F.R. $ 801.109)

Prescription Use ✓

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032544

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