2.h. 510(k) Summary

1) **Submitter's name:** D.F.Vasconcellos S.A.
Address: Avenida Indianópolis, 1706 – São Paulo – SP – Brasil
Contact person: Gilberto Alves Barral
Phone number: 11-55-11-5584 0411
E-mail: diretoria@dfv.com.br
Date: 05/27/2002

2) **Device's Name:** DFV CPG Colposcope
Proprietary Name: D.F.Vasconcellos S.A.
Usual Name: Colposcope
Classification Name: Colposcope

3) **Devices substantially equivalent**

There are many others devices already registered on FDA, substantially equivalent to Colposcope DFV, with the same physical and technical characteristics. The structure and material of devices are the same too. See the table above:

Device Name	Applicant Name	510(k) Number
Leica Colposcope	Leica Microscopy Systems	K000707
Leisegang Video Colposcope	Netoptix Corp.	K981958
IMT Loupe-Colposcope	Inventive Medical Technol	K963593
Video Colposcope/vertical	Welch Allyn, Inc.	K955635
Colposcopes and accessories	Leisegang Medical, Inc.	K940094
HM-0690 Colposcope	Hill-Med, Inc.	K932896
Jedmed KP6 Colposcope	Jedmed Instrument Co.	K884934
Wallach Convertible Colposcope	Wallach Surgical Devices	K871682
Wallach Zoom Colposcope	Wallach Surgical Devices	K853389
OCS-2 Colposcope	Olympus Corp.	K852980
Colposcope Model II	Dynatech Cryomedical Co.	K770896
Colposcope System	Richard Wolf Medical Instruments	K770697
Dynatech JD7/JD7P Colposcope	Dynatech Cryomedical Co.	K761205
Colposcope (Dynatech Colposcope)	Dynatech Cryomedical Co.	K760763

4) Description of the Device

Part	Function	Design
Stands	Serves to support the microscope head	Brass, aluminum, plastic, steel
Power supply	Supplies illumination to the microscope head	Electronic components, lamps, fiber optic cable
Microscope head	Amplifies and illuminates the human body region, which will be examined or observed by the physician	Brass, aluminum, steel, optical glass, plastic

Physical characteristics:

Colposcope	Galilean system
Binoculars	Straight Porro type 160 mm
Objective	300 mm
Eyepieces	Wide field type 12.5x adjustable
Magnifications	See table on page 9
Observation field	See table on page 9
Illuminated field	See table on page 9
Interpupillary distance	55-75 mm
Illumination field	Lamp 15V – 150W
Macro focus	With stand set movement
Micro focus	Gear rack and pinion manual
Head weight	3.8 kg to 6.0 kg
Vertical stroke	250 mm
Height between floor and objective	950 mm
Stand set weight	7 kg

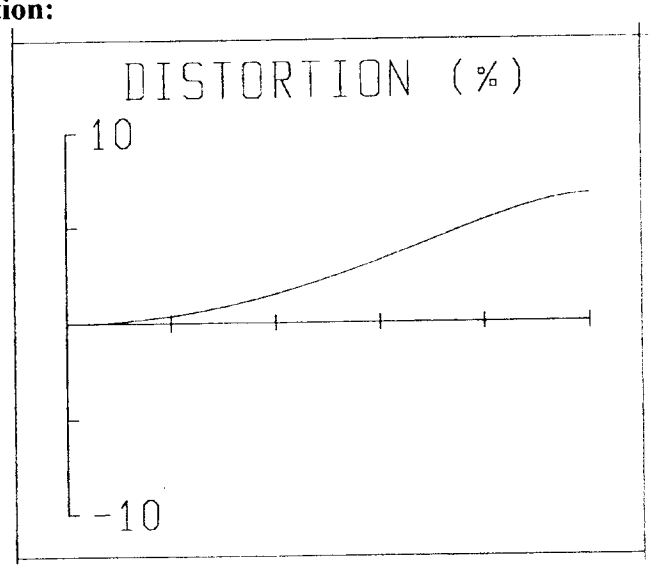
Resolution (reticule USAF 51):

Selector position	A	B	C	D	E
Resolved block	4-3	4-6	5-4	5-6	6-2
Line-pairs/mm	20	28	45	56	72

Depth of field (reticule USAF 51 and comparator clock):

Selector position	A	B	C	D	E
Depth of field (mm)	~ 15	~ 9	~ 3	~ 2	~ 1

Distortion:



5) Intended use of the device

A Colposcope is a device designed to permit viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. A Colposcope is used to diagnose and examine abnormalities of the vagina and cervix. The patient's population for which the Colposcope is intended is any person of the feminine sex.

6) Not applicable

Magnification Table

EYEPIECE	POSITION OF BUTTON	OBJECTIVE LENSES																							
		100				175				200				250				300				350				400			
		magnification		field		magnification		field		magnification		field		magnification		field		magnification		field		magnification		field		magnification		field	
		f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160	f125	f160
10X	6 (0.4)	5	7	35	26	3	4	58	45	3	3	66	52	2	3	79	65	2	2	99	78	2	2	115	90	1	2	132	103
	10 (0.6)	7	10	23	17	4	6	38	29	4	5	43	34	3	4	52	42	3	3	65	50	2	3	76	59	2	3	87	67
	16 (1.0)	12	16	14	11	7	9	24	18	6	8	27	21	5	6	32	26	4	5	40	32	4	5	47	37	3	4	54	42
	25 (1.6)	19	26	9	6	12	15	15	11	10	13	17	13	9	10	20	16	7	9	25	19	6	7	29	23	5	7	33	26
	40 (2.5)	29	40	6	4	17	26	10	7	16	20	11	8	13	16	13	11	10	13	16	13	9	11	19	15	8	10	22	17
12.5X	6 (0.4)	6	8	35	26	4	5	58	45	3	4	66	52	3	3	79	65	2	3	99	78	2	2	115	90	2	2	132	103
	10 (0.6)	10	13	23	17	6	7	38	29	5	6	43	34	4	5	52	42	3	4	65	50	3	4	76	59	3	3	87	67
	16 (1.0)	15	20	14	11	9	11	24	18	8	10	27	21	7	8	32	26	5	7	40	32	5	6	47	37	4	5	54	42
	25 (1.6)	25	33	9	6	15	19	15	11	13	16	17	13	11	13	20	16	9	11	25	19	8	9	29	23	7	8	33	26
	40 (2.5)	38	50	6	4	23	29	10	7	20	25	11	8	17	20	13	11	13	17	16	13	12	14	19	15	10	13	22	17
20X	6 (0.4)	10	13	20	15	6	7	33	26	5	7	37	29	4	5	45	37	3	4	56	44	3	4	65	51	3	3	75	58
	10 (0.6)	15	20	13	10	9	11	22	17	8	10	25	19	7	8	29	24	5	7	37	29	4	6	43	33	4	5	49	38
	16 (1.0)	24	32	8	6	14	18	13	10	13	16	15	12	11	13	18	15	8	11	23	18	7	9	26	21	6	8	30	24
	25 (1.6)	38	52	5	4	23	30	8	6	20	26	9	7	14	17	14	11	12	15	16	13	10	13	19	15	10	13	19	15
	40 (2.5)	59	80	3	2	35	46	5	4	31	40	6	5	26	32	7	6	21	27	9	7	18	23	11	8	16	20	12	10
ILLUMINATED FIELD		25				44				50				62				75				88				100			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

D.F. Vasconcellos S/A
% Mr. Jean M. Buchwald
Albee Import & Export of California
1990 NE 163rd Street, Suite 107
NORTH MIAMI BEACH FL 33162

Re: K021854
Trade/Device Name: DFV Colposcopes
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: 85 HEX
Dated: September 4, 2002
Received: September 11, 2002

Dear Mr. Buchwald:

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 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:

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" (21 CFR Part 807.97). 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

2.g. Indications for use

510 (k) Number: K021854

Device Name: **Colposcope**

Indications for use:

A Colposcope is a device designed to permit viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. A Colposcope is used to diagnose and examine abnormalities of the vagina and cervix. The patient's population for which the Colposcope is intended is any person of the feminine sex.

Prescription Use √

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021854

Concurrence of CDRH, Office of Device Evaluation (ODE)