JUN 23 1999

510(k) Summary
for
FIBERDENT CORPORATION ORASCOPE

K991011

1. SPONSOR

FiberDent Corporation
Suite B
3753 Varsity Drive
Ann Arbor, MI 48108

Contact Person: Neil Haven
Telephone: 734-213-7600

Date Prepared: March 25, 1999

2. DEVICE NAME

Proprietary Name: Orascope
Common/Usual Name: Dental Endoscope
Classification Name: Endoscope

3. PREDICATE DEVICES

Dental Medical Industries Telicam - K980474

Dental Vision Direct UltraCam - K933671

4. DEVICE DESCRIPTION

The Orascope consists of a flexible fiberoptic probe with sterile disposable sheath. The probe feeds magnified images from within the oral cavity. The flexible fiberoptic probe transmits the image information and light to and from the oral cavity. A light source transmits light through the fiber to illuminate the target area. Real time image information from the target area is transmitted through the fiber to a CCD color camera which sends this information to the flat screen display monitor to be viewed by the user. The flat screen display is mounted on a wheeled

flexible stand which can be positioned for optimum viewing comfort. The Orascope enhances the dentist's ability to see within the oral cavity.

The Orascope consists of the fiberoptic endoscope and sterile disposable sheath. A digital camera, monitor and video printer are also offered as accessories to the Orascope.

Orascope Fiberoptic Dental Endoscopes:
The Orascope consists of a flexible fiberoptic probe which contains both light-emitting fibers and image transmission fibers. The light emitting fibers gather light from a high-intensity light source affixed to the wheeled display stand. The light shines out the probe tip to illuminate the field-of-view for the image transmission fibers. The image transmission fibers transmit the image from the end of the probe tip back to the wheeled display stand where the color video camera creates the electronic image for display on the display screen. The Orascope is offered in both 0.9 mm and 1.8 mm tip outer diameter sizes. Each probe contains light conducting fibers for the illumination of the probe's field-of-view as well as image conducting fibers for optical transmission of the image of the field-of-view to the camera.

Sterile Disposable Sheath:
The sterile disposable sheath is a single use closed end sheath which covers the end of the probe for about 100 mm. This sheath has been subjected to USP Class VI biocompatibility test results and cytotoxicity testing. Viral Penetration testing has been performed on the sheaths. The test results showed that virus (bacteriophagy) did not penetrate the film or the heat seals of the sheaths tested.

Camera:
The camera offered with the Orascope is a Panasonic GP-US522 three-chip color CCD camera with remote head. The GP-US522 is a standard three-chip color CCD camera with a resolution of 768 (H) x 494 (V). The camera operates on 12 VDC. The camera is used to capture a video image from the Orascope fiber-optic probe(s) and provide an S-Video signal for display by the video monitor.

Video Monitor:
The video monitor offered with the Orascope is a National Display Systems 15" XGA Flat Panel Video Display Monitor Model #DSW-X15-N. This flat-screen video display monitor operates from the S-Video signal provided by the camera. The monitor operates on 12 VDC.

Light Source:

The light source is a Cuda Products Corporation dual channel Xenon-quality fiber-optic light source. The MX2-300 operates on 120 VAC and provides illumination from one of two metal-halide bulbs. Dual channel means that the light source contains two bulbs. If one bulb burns out during a procedure, the light source can be configured so that the second bulb can be used within seconds. The light from the bulb is reflected onto a fiberoptic light-guide which is plugged into the cable receptacle on the front of the MX2-300.

5. INTENDED USE

The FiberDent Orascope™ is a non-diagnostic fiberoptic visualization device used to illuminate and magnify dental surfaces.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The FiberDent Corporation Orascope device is substantially to the Dental/Medical Diagnostic Systems Incorporated Telicam Intraoral Video Camera, subject of K980474 and the Dental Vision Direct, Inc UltraCam, subject of K933671.

The Orascope and the predicate devices are similar in intended use in that they are all intended as non-diagnostic endoscopic cameras to illuminate and magnify dental surfaces. They are all indicated for use in the dental office.

The Orascope and the predicate devices are similar in technological characteristics in that they all consist of a non-diagnostic intraoral video camera and monitor for viewing images. All three devices use a camera and monitor. Both the Orascope and the Telicam provide a sterile disposable sheath with the probe whereas the UltraCam has an autoclavable tip. Both the Orascope and the Telicam require a fiberoptic light source whereas the UltraCam does not use a fiberoptic light source.

The principle of operation of the proposed and predicate devices are the same in that they all transmit and image from the target oral cavity area to camera to a display monitor. Both predicate devices offer a printer for viewing images whereas the Orascope system does not.

7. PERFORMANCE TESTING

The Orascope Dental Endoscope and accessories have been subjected to and passed the following electrical safety and EMC/EMI Testing:

• Radiated Electromagnetic Immunity	EN 61000-4-3 & ENV 0204
• Electromagnetic Interference	EN 55022
• Conducted Electromagnetic Immunity	EN 61000-4-6:1996
• Power Frequency Magnetic Field Immunity	EN 61000-4-8:1993
• Electrostatic Discharge Immunity	EN 61000-4-2:1995
• Limits for Harmonic Current Emissions	IEC 1000-3-2:1995
• Voltage Dips, Interrupts and Variations	IEC 1000-4-11:1994
• Surge Immunity	IEC 1000-3-2:1995
• Electrical Fast Transient/Burst Immunity	EN 61000-4-4:1995

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1999

FiberDent Corporation
c/o Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachuettes 02760

Re: K991011
Trade Name: Orascope™
Regulatory Class: I
Product Code: EIA
Dated: March 25, 1999
Received: March 26, 1999

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: FiberDent Corporation Orascope™

Indications For Use:

The FiberDent Corporation Orascope™ is a non diagnostic fiberoptic visualization device used to illuminate and magnify dental surfaces.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991021

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)