K042438

NOV - 8 2004

510(k) Summary

superDimension Ltd.
510(k) Submission
Bronchus
August 13, 2004

1. Submitter Information

Name: superDimension Ltd.

Address:

14 Shenkar St., POB 2045
Herzliya 46120
Israel

Tel. +972-(0)9-971-3700
Fax +972-(0)9-971-3701

Contact person:

Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Tel.: 201-727-1703
Fax: 201-727-1708

Date prepared: August 30, 2004

2. Name of Device

Trade Name: superDimension/Bronchus
Common Name: Bronchoscope
Classification name: Bronchoscope (flexible or rigid)
Regulation: 21 CRF 874.4680

3. Equivalent legally- marketed devices:

Ultraguide CTG 2000sa K022354 JAK
Olympus UM-2R/3R K982323 ITX
Olympus BF 1T160 K023984 EOG - ENT

4. Description

The superDimension/Bronchus is a device that guides a bronchoscope and bronchial tool to a target in the bronchial tree on a path indicated by CT scan, and to visualize the interior of the tree and target

5. Intended Use

Displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools in the pulmonary tract. It does not make a diagnosis and is not an endoscopic tool

6. Performance Data

Non – clinical tests

The superDimension/Bronchus satisfies the requirements of EN60601-1 and EN 60601-1-2. The entire system has had extensive bench testing.

Clinical tests

The superDimension/Bronchus has had both animal tests and a clinical evaluation.

7. Conclusion

The superDimension/Bronchus is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

superDimension Ltd.
% Mr. George Myers
President
Medsys, Inc.
377 Route 17 S
HASBROUCK HEIGHTS NJ 07604

Re: K042438
Trade/Device Name: superDimension/Bronchus
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: September 5, 2004
Received: September 8, 2004

Dear Mr. Myers:

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/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

Indications for Use

510(k) Number (if known): K042438

Device Name: superDimension/Bronchus

Indications For Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools in the pulmonary tract. It does not make a diagnosis and is not an endoscopic tool.

Not for pediatric use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042438