APPENDIX 9: 510 (K) SUMMARY

K024103

510(k) Summary
As required by 807.92
For CALM Patterns
Prepared on December 2, 2002

Submitted by: INDEC Systems, Inc.
505 E. Evelyn
Mt. View, California 94041

Tel. 650-903-9755 Fax: 650-919-0150

JAN 2 4 2003

Contact Person: Carol Hubler

Device Trade Name: **IVUS Plus**

Common Name: digital image display system for intravascular ultrasound

Classification: Picture Archiving and Communication System, Class II Sec. 21 CFR 807.92

Predicate Device: Resolve Option for the Oracle In-Vision Intravascular Imaging System K965223 and Galaxy Intravascular Ultrasound System K980851

Manufactured by: Jomed Corporation, 2870 Kilgore Road, Rancho Cordova, CA 95670
Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760-1537

Description of the Device: **IVUS Plus** will function as an accessory to **ClearView** and **Insight** (K891386 and K921750), Boston Scientific's intravascular ultrasound imaging systems. **IVUS Plus** adds digital image review capability and full-length longitudinal display with full image rotation and mensuration functions.

Intended Use for the Device: It is indicated for use in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Substantial Equivalence to Predicate Device: The IVUS Plus add on accessory to the ClearView ultrasound system is substantially equivalent in intended use, design and operation characteristics to the following currently marketed devices:

Endosonics In-Vision (Now called Jomed) with Resolve (K965223),
Boston Scientific (formerly CVIS) Insight II (K921750) with Automatic Pullback Device (K933517) and Longview (K930311)
Boston Scientific Galaxy system (K980851)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

Ms. Carol Hubler
General Manager and Vice President
INDEC Systems, Inc.
505 East Evelyn, Suite D
MOUNTAIN VIEW CA 94041

Re: K024103
Trade/Device Name: IVUS Plus
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 2, 2002
Received: December 12, 2002

Dear Ms. Hubler:

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

Ver/ 3 - 4/24/96

Applicant: _INDEC Systems, Inc._____

510(k) Number (if known): _____

Device Name: IVUS Plus_____

Indications For Use:

IVUS Plus is a digital image processing accessory to Boston Scientific's intravascular ultrasound imaging systems, **ClearView** (K891386) and **Insight** (K921750). It adds full-length longitudinal digital display capability, full image rotation capability, and mensuration functions. It is indicated for use in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign Off)

Division of Reproductive, Abdominal, and Ophthalmic Devices

510(k) Number 1202403

Prescription Use ✓