K102192

6. 510(k) Summary

FEB 2 3 2011

Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. Company Phone: (905) 602-4875; ext 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: July 27, 2010

Device Identification

A. Device Trade Name: InDiscal™ Digital Manometer

B. Device Common Name: Piston Syringe Discography Device

C. Classification Name: 21 CFR 880.5860

D. Device Class: Class II

E. Device Code: FMF

Identification of Predicate Device

Device name	Manufactured by	510(k) number
Atrion Medical QL™ Fluid Dispensing Syringe	Atrion Medical Products Inc.	K020333
Integra Accumeter	Integra ™ Pain Management	K033739

Device Description

The InDiscal™ Digital Manometer is a sterile, single-use device that is used to dispense fluids into and monitor pressure in vertebral discs during spinal procedures such as discography. The device consists of a plastic syringe with a screw-type plunger and locking lever, a rotating palm grip that controls the plunger, a manometer with a digital LCD screen and a connecting tube.

Indications for Use

The InDiscal™ Digital Manometer is indicated to be used for dispensing fluids into the intervertebral disc and monitoring the pressure of those fluids during discography procedures in symptomatic patients with suspected intervertebral disc pathology.

Substantial Equivalence

The intended use of the InDiscal™ Digital Manometer is substantially equivalent to the intended use of the Integra Accumeter and the design of the Atrion Medical QL™ Fluid Dispensing Syringe predicate devices. The following verification and validation tests have been conducted in order to demonstrate substantial equivalence to the predicate devices.

Mechanical Testing

- Ingress Protection
- Pressure Vessel
- Push Test
- Drop test
- Molding Stress Relief Test

Electrical Testing

- Burn-in Test
- Dielectric Strength
- Pre-EMC Testing: Accuracy Test
- Pre-EMC Testing: Functionality Test
- Radiated Emissions
- Electrostatic Discharge (ESD)
- Magnetic Immunity
- Radiated Immunity
- Post-EMC Testing
- Battery Life and Low Battery Alarm Test

Accuracy testing

Accuracy testing of the pressure gauge was performed in order to demonstrate the accuracy of the InDiscal Digital Manometer under normal and low battery voltage conditions.

General testing

General testing was performed to verify compliance of the InDiscal Digital Manometer to design inputs.

Software validation

Software validation was performed under normal and low battery voltage conditions.

The InDiscal Digital Manometer passed all verification and validation tests. The data and information presented in this application support a determination of substantial equivalence and,

therefore, the market clearance of the InDiscal Digital Manometer through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Meghal Khakhar
Manager, Regulatory Scientific Affairs
Baylis Medical Company, Incorporated
2645 Matheson Boulevard East
Mississauga, Ontario
CANADA L4W S4

FEB 2 3 2011

Re: K102192
Trade/Device Name: InDiscal™ Digital Manometer
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: February 15, 2011
Received: February 16, 2011

Dear Ms. Khakhar:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

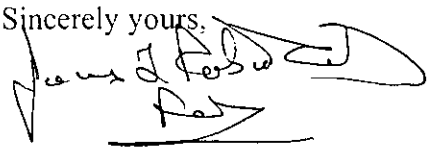
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: InDiscal™ Digital Manometer

Indications for Use:

The InDiscal™ Digital Manometer is indicated to be used for dispensing fluids into the intervertebral disc and monitoring the pressure of those fluids during discography procedures in symptomatic patients with suspected intervertebral disc pathology.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BC RZC Feb 23, 2011

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102192

Page 1 of 1