

## **NCMD Update – April 2005**

### **NCMD EVENT OUTLOOK**

#### **Medical Device Forum – “FDA Regulatory Update”**

How does the FDA regulate combination products such as drug-eluting stents and metered dose inhalers? What is the best practice for submitting a 510(k)? How do I seek resolution for a regulatory dispute? On May 16, three FDA representatives and a local medical device company will help answer questions like these.

Where and when? **North Carolina Biotechnology Center, May 16, 2005**

What's the agenda? **4:30-5:00 registration, 5:00-6:45 presentations and open panel discussion, 6:45-8:00 reception**

Who are the speakers?

**Patricia Love**, Associate Director, FDA Office of Combination Products

**Heather Rosecrans**, Director of 510(k) Staff, FDA Office of Device Evaluation

**Les Weinstein**, CDRH Ombudsman, FDA Office of the Center Director

**Tammy Carrea**, Director, Regulatory Affairs, Sichel Technologies

To register for this event, please visit [www.ncmedicaldevice.org/events.html](http://www.ncmedicaldevice.org/events.html)

### **RTP Medical Device Manufacturer Looking to Hire**

Teleflex Medical, a \$740 million international medical and surgical device manufacturer with more than 6,000 employees worldwide, expects to have more than 150 openings in Research Triangle Park in the following areas: medical device industry sales; marketing and product management; information technology; engineering (product development and manufacturing); finance and accounting/contracts administration; quality and regulatory assurance; and manufacturing operations. Interested candidates may obtain more information at the company website: [www.teleflexmedical.com](http://www.teleflexmedical.com). Questions may be submitted to: [jobs@teleflexmedical.com](mailto:jobs@teleflexmedical.com).

Teleflex Medical, a division of Teleflex Incorporated, is a global supplier of medical devices, surgical instruments, and disposable medical products. Teleflex Medical markets Rusch and Hudson RCI healthcare supplies, as well as Deknatel, KMedic, Pilling, and Weck surgical instruments and medical devices. Teleflex Medical OEM is a preeminent global outsourcing provider that focuses on medical devices and orthopedic surgical instruments. OEM brands include KMedic, Beere, Deknatel, and TFX OEM. The division also offers on-site operating room services for integrated health networks.

### **Johnson & Johnson and Raleigh based Closure Medical Announce Acquisition Agreement**

Johnson & Johnson and Closure Medical Corporation, a global leader in biomaterial-based medical devices, recently announced a definitive agreement whereby Closure Medical will be acquired in a cash-for-stock exchange. Closure is expected to operate as a stand-alone entity reporting through Ethicon, Inc., a J&J company, with whom Closure has worked since 1996 on the development of topical adhesives.

Closure designs, develops, and manufactures a number of medical adhesives and delivery devices based on a proprietary medical-grade cyanoacrylate technology for specific applications in wound care and wound closure. This technology is found in the family of DERMABOND® Topical Skin Adhesive products, which are marketed by Ethicon under an exclusive distribution agreement. It is also found in BAND-AID® Liquid Bandage. Closure's formulations offer several advantages, including speed, ease-of-use, and performance, versus other products.

“This acquisition demonstrates Ethicon's commitment to further expand the successful DERMABOND business and advances our efforts in topical adhesives and surgical sealants,” said Dennis N. Longstreet, Company Group Chairman for Ethicon, Inc. “The capabilities and experience Ethicon expects to gain from this transaction can significantly contribute to the company's sustained success in these important segments.”

Ethicon and Closure have both focused on further developing topical adhesives. Closure's OMNEX™ Surgical Sealant recently received European CE Mark approval for use as an adjunct to sutures to achieve hemostasis in peripheral vascular surgery. Approval for a similar indication in the U.S. is anticipated in 2006.

“Closure Medical and Ethicon have enjoyed a partnership to provide better health care and fulfill the unmet needs of patients and physicians around the world,” said Daniel A. Pelak, Closure's President and CEO. “We believe this acquisition will provide benefits to both our employees and shareholders.”