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Panelists see cell counters as not yet ready for waiver

By MARK McCARTY
***Medical Device Daily* Washington Editor**

GAITHERSBURG, Maryland – The trick for the modern government agency is knowing when to insert itself in the process and when to get out of the way. This was the undertone in last Friday's meeting of the FDA's hematology and pathology devices advisory committee, which examined whether analytical equipment designed to render a complete blood count (CBC) and a differential blood cell count (CBC/diff) should be permitted in the absence of a clinical lab professional.

According to FDA's meeting documents, no waiver for this type of equipment has been granted up to now because no manufacturer has made a cell counter "that is capable of successfully controlling the many sources of analytical error that can result from the lack of oversight by a laboratory professional," even when a physician is present.

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Short on funding

PLC Systems delays pivotal trial for RenalGuard system

By LYNN YOFFEE
***Medical Device Daily* Staff Writer**

Another victim of the deflated market, **PLC Systems** (Franklin, Massachusetts) is tightening its belt and deferring the start of a U.S. pivotal trial for its RenalGuard product, which would be the first real-time, automated fluid-balancing system to prevent contrast-induced nephropathy (CIN).

PLC will continue to support an investigator-sponsored clinical trial ongoing in Italy as well as the limited market launch of RenalGuard in Europe, which began in the first quarter of this year, both of which are focused on the CIN prevention market.

"We felt we didn't have sufficient funding to finish the [pivotal U.S.] trial and you don't want to put hospitals in an uncomfortable position. The right thing to do is to delay

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Report from Europe

Zurich study cites reduced radiation of dual-source CT

By JOHN BROSKY
***Medical Device Daily* European Editor and Staff Reports**

A 120-patient study conducted at the **University Hospital Zurich** (Zurich, Switzerland) has found that a novel non-invasive step-and-shoot (SAS) mode for the diagnosis of coronary artery stenosis provides highly accurate results compared to the conventional clinical practice requiring invasive coronary angiography while significantly reducing radiation exposure to patients.

The results of the study were published in the June issue of *Heart*, the journal of the **British Cardiovascular Society** (London).

The single-center study marks the first clinical trial of the Somatom Definition from **Siemens Healthcare** (Erlangen, Germany), equipped with two X-ray tubes and support software capable of characterizing tissue and their densities (*Medical Device Daily*, March 13, 2008).

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Ekos says EkoSonic ES device is a 4-times-faster clot-buster

By AMANDA PEDERSEN
***Medical Device Daily* Staff Writer**

Ekos (Bothell, Washington) has launched a device that it says provides a safer, faster and more complete way to remove dangerous blood clots.

According to the company, the recently FDA-cleared EkoSonic endovascular system (ES) with Rapid Pulse Modulation (RPM) is the only endovascular system that can deliver microsonic energy and thrombolytic drugs simultaneously, with no evidence of thrombus breakage or hemolysis.

Robert Hubert, president/CEO of Ekos, told *Medical Device Daily* the EkoSonic stands out from other endovascular systems on the market because most of these other devices are mechanical and therefore not as safe as the EkoSonic ES.

He said that Ekos' technology avoids hemolysis, a complication often associated with lengthy mechanical procedures and associated with kidney failure complications.

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Ekos

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"Unlike mechanical devices, Ekos technology does not fracture the thrombus or damage red blood cells," Hubert said. "Faster clot dissolution means a lower lytic drug dosage, resulting in fewer complications. Physicians can treat patients in less time, with even greater clinical confidence."

The technology uses ultrasound to temporarily loosen and separate the fiber of the blood clot – the fibrin – for more blood clot permeability, according to Ekos. The ultrasound also helps push the drug deep into a blood clot to accelerate thrombolysis and dissolve the clot, the company said.

Using ultrasound to open up and dissolve blood clots is a technique that has been studied for four decades, Hubert said. Ekos has developed a way to miniaturize the ultrasound devices that are embedded inside the catheter, he said.

Also, the catheter itself is an "intelligent drug-delivery catheter," which he described as designed to automatically sense what is happening during its use in real time.

The company's Mach 4 device – an earlier generation of the technology — has been on the market for two years, Hubert noted. The difference between it and the EkoSonic is that the new device offers the RPM strategy, a new method of attacking the clot by disrupting it two times faster than the Mach 4 and four times faster than conventional catheter-directed thrombolysis.

In addition to its RPM technology, the EkoSonic ES design features an advanced control unit with an easier, more intuitive user interface, making set-up and operation simple, EKOS said. EkoSonic ES is also compatible with the EkoSonic Mach 4.

The Mach 4 was specifically created to be compatible with the RPM technology, the company noted. The Mach 4 offers a variety of treatment zone options. Each Mach 4 consists of a MicroSonic Core within an intelligent drug-delivery catheter. This combination device enables the system to deliver microsonic energy and drugs simultaneously to accelerate clot dissolution, Ekos said.

The EkoSonic system is FDA-cleared for controlled and selective infusion of physician-specified fluids, including thrombolytic, into the peripheral vasculature. It is used to treat patients with peripheral arterial occlusions and deep vain thrombosis.

The company says the technology also may some day change the way ischemic stroke patients are treated. In 2006 Ekos received a grant from the National Institute for Neurological Disorder and Stroke, a division of the National Institutes of Health, to develop an ischemic stroke therapy that provides faster restoration of blood flow to the brain tissue.

Ekos said preclinical studies demonstrated that the addition of ultrasound contrast agents to ultrasound accelerated enzymatic thrombolysis and so could significantly augment the rate of clot lysis.

According to EKOS, physicians have responded favorably over the past three years after performing nearly 6,000 cases using the EKOS technology.

"We predict that the EkoSonic will become the new gold standard to treat patients with vascular thrombosis," Hubert said.

Major U.S. medical centers using the EkoSonic ES, according to Ekos, include **Baptist Cardiac & Vascular Institute** (Miami, Florida), **Cleveland Clinic Foundation**, **Dartmouth-Hitchcock Medical Center** (Lebanon, New Hampshire), **Emory University Hospital** (Atlanta), **Massachusetts General Hospital** (Boston), **The Methodist Hospital** (Houston), **University of Illinois Medical Center at Chicago**, and the **Swedish Medical Center** (Seattle). ■

Europe

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FDA okays Inion systems

Inion (Tampere, Finland) said it has received FDA clearance for its biodegradable graft containment systems for spinal fusion procedures.

Marketing approvals have been received for the S-I anterior cervical fusion system, S-I double-level plate and S-2 anterior thoraco-lumbar fusion system.

These systems consist of biodegradable plates and screws, which are designed for bone graft containment in spinal fusion procedures. Such procedures are carried out as a treatment for a range of spinal conditions including ruptures and displacement of inter-vertebral discs.

Inion's S-I and S-2 graft containment systems include implants intended for use along the entire length of the spine in conjunction with traditional rigid fixation. ■

MED-TECH NEWS AND NOTES

Dynatronics gets Nasdaq notification

Dynatronics (Salt Lake City) said the company has received a letter from Nasdaq stating that for the last 30 consecutive business days, the bid price of its common stock has closed below the minimum $1 a share requirement for continued inclusion under Nasdaq's marketplace rules.

The company will be given 180 calendar days, until Dec. 22, to regain compliance. If, at anytime before Dec. 22 the bid price of the common stock closes at $1 a share or more for a minimum of 10 consecutive business days, Nasdaq will provide written notification that compliance has been regained.

Dynatronics makes medical devices and orthopedic soft goods and supplies.