DELTEX MEDICAL
Group plc

Steve Phurrough, MD, MPA, Director
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mailstop C1-09-06
Baltimore, MD 21244

August 22, 2006

Dear Mr Phurrough,

Formal request to reconsider NCD (Ultrasound Diagnostic Procedures 220.5)

On behalf of Deltex Medical Group plc, this submission is a formal request for reconsideration of the Centers for Medicare and Medicaid Services national coverage Determination (NCD) Ultrasound Diagnostic Procedures 220.5.

This non-coverage determination means that reimbursement for the use of esophageal monitoring to determine cardiac output and for hemodynamic management is not possible. Deltex Medical's CardioQ esophageal Doppler monitor is the most widely used monitor of its kind in the world. Deltex Medical has worked with the Centers for Medicare and Medicaid Services to try and understand the reasoning behind this non-coverage determination but no supporting documentation related to the determination is available.

Deltex Medical believes that the determination pre-dates the commercial availability both of the CardioQ and its predecessor devices (the EDM I and EDM II), much, if not all, of the validation data and all of the peer-reviewed, randomized controlled clinical trial data.

Deltex Medical believes that the overwhelmingly positive published medical literature (including eight randomized controlled trials) and widespread use of its technology in the rest of the world indicates that this decision is out of date and needs to be reversed. Additionally, Deltex Medical believes that reimbursement of this technology will drive its usage in the USA, leading to significant benefits for US patients and economic advantages to the US Healthcare system.

Deltex Medical Group plc ◆ Terminus Road ◆ Chichester ◆ PO19 8TX ◆ West Sussex ◆ United Kingdom
Phone: +44 (0) 1243 774837 ◆ Fax: +44 (0) 1243 532534 ◆ Customer Service: 0845 085 0001 ◆ www.deltexmedical.com
Registered in England & Wales No: 390 2895 VAT Registration No: GB 615 4000 89

Deltex Medical believes that this submission provides a comprehensive review of esophageal Doppler-based determination of cardiac output and the use of this technology to improve outcomes through hemodynamic optimization; a review of the data related to the safety and efficacy of the technology; a technical overview and; a review of the current peer-review published clinical data from randomized clinical trials. Deltex Medical believes that this submission provides sufficient evidence to warrant a reversal of the current non-coverage determination cited above.

We propose that the CardioQ be used in those patient groups that have been studied; specifically ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization. Based on the studies reviewed in the submission, there are many surgical patient groups who benefit from having their hypovolemia diagnosed and treated with the CardioQ. These groups include patients undergoing:

- Cardiac surgery
- Colorectal surgery
- Major general surgery
- Major urological surgery
- Major gynecological surgery
- Orthopedic hip surgery

The benefits of fluid optimization would logically extend to patients at similar risk of occult hypovolemia as those in that have been enrolled in clinical trials. Patients with an anticipated blood loss >500cc, or procedures with an anticipated duration in excess of one hour from induction to recovery room, or with a preoperative ASA class of IIE or higher would likely benefit from treatment guided by the CardioQ.

We request that the CardioQ be covered under physician services and inpatient services. Coverage for physician services is essential to encourage the use of this device that improves morbidity and length of stay, and this care is provided most commonly in an inpatient setting. We anticipate that anesthesiologists and ICU physicians will be the most regular users.

We look forward to working with the CMS to further discuss the substantial clinical and economic benefits that the CardioQ can bring to Medicare patients and the wider US healthcare system. If you need any further information please do not hesitate to contact me.

Yours sincerely

Andy Hill
Chief Executive
Deltex Medical Group plc