

March 7, 2006

Domini Cassis
CDRH (HFZ-215)
Food & Drug Administration
1350 Piccard Dr.
Rockville, MD 20850

Ms. Cassis:

The following is an outline of the presentation that we plan to make at the March 29, 2006 public workshop concerning the proposal for OTC sales, distribution, and unsupervised use of hand-held fetal Doppler devices.

A. Introduction

Background on Summit Doppler. Why does Summit Doppler have an interest in the Fetal Doppler OTC issue?

1. History of Summit Doppler
2. Types of products we design and manufacture
3. Description of our distribution channels
4. Disclosure of how we may be effected financially based on the FDA's decision.

B. Foundation of Fetal Doppler Safety

Fetal Doppler has been in use for over three decades and the associated risk has been deemed acceptable by clinicians in the United States. How has this been achieved?

1. Safety of ultrasound is not inherent – it is a shared responsibility between clinicians, industry and the FDA.
2. Exposure Limits - I_{SATA}
3. Duration of use and the principle of “ALARA”
4. GMP's and 510(k)

C. OTC and Possible Safety Effects

There are number of safety issues that should be considered as part of the OTC decision making process.

1. ALARA - Conflicts, mitigation, and labeling
2. Exposure - Increased acoustic output and a potential “race to the bottom”
3. GMP’s / 510(k) – Do we have adequate resources to insure enforcement?
4. AIUM position on Entertainment Ultrasound

D. Evidence of an Emerging Issue

Several issues have emerged recently that indicate our concerns about OTC safety issues should be taken seriously.

1. De facto OTC devices are being sold in the USA now, and they don’t establish a good record.
 - a. In opposition to the ALARA principle one manufacturer instructs, “Repeat the procedure as often as you like making sure to add gel as needed”.
 - b. Illustration of a child using a fetal Doppler
 - c. Lack of warnings, indications for use, contraindications, manufacturer contact information
2. Entertainment Use of Ultrasound
 - a. *Product X* “...should not be used by you in any way for diagnostic or other medical purposes.”
 - b. At least one keepsake ultrasound company selling unit without 510(k) “specially designed for personal use”
3. The *ebay* Problem
 - a. Lack of 510(k)’s
 - b. Complaint handling – a break in the system
 - c. The need for a level playing field – a regulatory/business issue

E. Conclusion

Patients rely on clinicians, device manufacturers and the FDA for delivery of safe, effective medical products. Existing and potential problems we have identified point to the likelihood of a poor outcome should OTC sales become a reality. We fear a situation where patients may be subjected to substantially unsafe products, clinicians may lose access to high quality professional products, and the FDA will be faced with a new and difficult enforcement issue. Summit Doppler Systems requests that fetal Doppler devices remain subject to prescription use.

I expect this presentation to require about 15 minutes. Please let me know prior to March 10 if you require a level of detail beyond what I have provided in the outline above.

Sincerely,



Dave Jones
V.P. of Engineering
Summit Doppler Systems, Inc.

Additional Presentation Materials:

1. Babycom literature -- downloaded 2/09/06
2. Anticipation Ultrasound Studios web site -- downloaded 2/09/06
3. Ebay item 7595411974 (Hi Bebe Doppler) 3/02/06
4. Ebay item 7593981445 (CHX-3A Doppler with Alarm Function) 3/02/06
5. AUIM statement on Entertainment Ultrasound