Questions and Answers Regarding FDA and ZOLL’s Regulatory Status

What is the FDA role in governing the approval and manufacture of medical devices?

- FDA is in charge of clearing medical devices for sale. They also regulate the quality of the manufacturing, monitor device problems and approve changes to device design that affect safety or efficacy. They cooperate with international agencies.

How does FDA control quality of manufacturing?

- FDA enforces US Government regulations that mandate current Good Manufacturing Practices (GMP). These regulations provide requirements for designing, manufacturing, documenting and changing medical devices. Manufacturers establish a Quality System that complies with the regulations. FDA inspects manufacturers on a regular basis to audit their Quality Systems to ensure compliance.

How are deficiencies found during inspections addressed?

- At the end of an inspection, FDA provides the manufacturer with a list of deficiencies that they believe require corrective action. This list is documented on form 483. Typically a manufacturer will submit a corrective action plan to the FDA and work to address the deficiencies as quickly as possible.

When was the last time ZOLL was inspected?

- ZOLL was last inspected in July 2006. While this should not be construed as an FDA “stamp of approval”, the FDA found no deficiencies during the inspection and no Form 483 was issued. We believe this Level 2 “comprehensive” inspection was part of an industry-wide review. Recent disclosures from Medtronic/Physio Control indicate they underwent a similar inspection in May 2006 culminating in the current voluntary suspension of manufacturing.

What is a Warning Letter?

- Should the FDA feel that deficiencies found during an inspection are critical to the safety or efficacy of a product, or that a manufacturer is not addressing deficiencies in an adequate manner, they may issue a Warning Letter. A Warning Letter is a strong notice to a manufacturer that its practices are deficient and must be corrected immediately. ZOLL received a Warning Letter in 1997 which was closed out to the FDA’s satisfaction quickly without further action.

Does a Warning Letter Mean a Product is not Safe?

- A Warning Letter may cover issues as seemingly innocuous as failure to document a procedure or can deal with items that seem more serious such as product. Paperwork and process issues are serious; in that accurate record keeping and documentation is an indication that manufacturing is under control. Failure to address issues in Warning Letters can lead to further FDA action, including removal of clearances to market, product seizures, export restrictions, product recalls and delays on new clearance applications for new products to be sold.

What is ZOLL’s regulatory status today?

- ZOLL has no Form 483 issues, Warning Letters or other open issues pending with the FDA. Our operations and ability to meet customer’s needs has never been interrupted due to regulatory issues. We have never been taken to court by the FDA or ever had legal action threatened by the FDA. We have a full disclosure policy to the FDA for all product complaints, and we believe we are the most transparent of any company in our industry.

- ZOLL is in full compliance. We will maintain full compliance. Improving our quality system is an ongoing process at ZOLL. We understand that our industry is under close scrutiny, and we must continue to do more. While past success is not a guarantee of future performance, we believe that our historical philosophy and approach to FDA compliance, as well as recent inspection results, are evidence that we are doing the right things in this area.