October 20, 2010

Regarding: Medical Device Directive 2.4/1, revision 9

CERUS INFORMS

On July 16, 2010, the Borderline and Classification Committee for the European Community published their recommendations for the classification of the pathogen inactivation and pathogen reduction technologies. Technologies, addressed by the Committee, may use a variety of methods to inactivate pathogens such as psoralen-derivatives, riboflavin, ethylene imines and methylene blue. Regardless of the inactivation process, the Committee recommends all of these technologies to be classified as Class III medical devices under rule 13. The Committee recommendation provides guidance to assure all technologies meet the same rigorous standards regarding supporting data and regulatory review required to make product or label changes. The Borderline and Classification Committee provides their input as recommendations expecting the industry and regulatory bodies to adopt the recommendations voluntarily to avoid the time and expense of developing a legal framework. While Cerus fully supports this process, not all companies are currently in compliance with the recommendations of the Committee and may lack the necessary data to qualify for the Class III certification. The lack of a Class III certification raises serious questions regarding the adequacy of the technology in demonstration of safety and efficacy.

Cerus Corporation always endeavors to meet the highest standards regarding the development, testing and clinical evaluation of the INTERCEPT Blood System for pathogen inactivation treatment of transfusion components. This practice assures safety and efficacy of both the device and the biological product derived from the use of the device.

INTERCEPT received a Class III CE mark for its platelets product in 2002 and for plasma in 2006. In compliance with the European requirements, the regulatory oversight for Cerus INTERCEPT technology is provided by a Notified Body which is TÜV, headquartered in Germany and a Competent Authority which is AFSSAPS, in France. To maintain compliance with requirements of the CE marking, Cerus must receive regulatory review and approval by both TÜV and AFSSAPS for any change in manufacturing, labeling, or clinical claims. To approve any change to the license, TÜV and AFSSAPS require detailed descriptions of the change, clear justification for the request and appropriate data to meet the rigorous standards of regulatory review. In addition, all Cerus locations of operations are inspected annually by TÜV for compliance with ISO13485; every third year, the sites are recertified in a detailed inspection also by TÜV. The recertification requires several days of auditing records and the facilities to assure current good manufacturing practices and standards are maintained to meet the state of the art. Class III CE marking represents the highest standards for device marketing and is verified by oversight of external regulatory reviews.

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We, at Cerus would like to reassure all of our customers and prospective customers of our commitment to meet or exceed all regulatory requirements. We are also prepared to address any customer inquiry regarding certification and/or associated requests for data. Please don't hesitate to contact your local Cerus representative in case you have any further questions.

Yours sincerely,

Your Cerus Team