



MEMORANDUM

FROM: Moira Barton, Sr. Director of Regulatory Affairs

RE: SUD Reprocessing in Canada

DATE: April 2007

Health Canada, the regulating agency for medical devices in Canada, has different registration (licensing) categories for medical device manufacturers wishing to market their device(s) in Canada. The eligibility requirements for registration are that the manufacturer have ISO 13485 certification and have a Canadian Medical Devices Conformity Assessment System (CMDCAS) certificate.

Currently, Health Canada does not have a category, or licensing mechanism, for "Reprocessors" although Ascent is working with representatives of Health Canada to address this limitation. In the interim, Health Canada has stated that because Ascent Healthcare Solutions is ISO 13485 certified and has a Canadian Medical Devices Conformity Assessment System (CMDCAS) certificate we are able to reprocess devices for Canadian hospitals. Ascent also complies with all international exporting requirements and we provide our U.S. FDA 510(k) clearance documentation and device listing numbers for our products to Health Canada.

For further information or to answer additional questions on licensure I recommend contacting Don Boyer, Manager, Licensing Services Division at Health Canada. He can be reach at 613.957.7090.