



TO: *Pierre Saverot, Nuclear Regulatory Commission*

FROM: *Alex Ossipov*

DATE: *May 18, 2012*

SUBJECT RE: *Limited Use of the General Electric Model No. 1500 Package in support of reloading the STAAR SURGICAL Aliso Viejo Facility irradiator*

Dear Mr. Saverot,

STAAR Surgical Company develops, manufactures and sells ophthalmic medical devices implanted by surgeons in patients during refractive, cataract and glaucoma-related surgeries. Company's main products are unique foldable small incision ophthalmic implants. The Company has developed unique, (no other analogs in world) biocompatible Collamer material that greatly assists patients. The Collamer manufacturing process to create our Collamer material requires using of high dose irradiator exclusively for the special synthesis phases. Such products are the back-bone to STAAR's proprietary products range and allow STAAR Surgical to employ workers in the U.S. and compete effectively around the world.

It is critical that STAAR's high dose irradiator be reloaded to provide enough of the high dose rates necessary to support our California-based manufacturing team in the production of our current medical devices and to enable our California-based research workers during their R&D efforts. Since its installation in 1997 the irradiator located in Aliso Viejo that we use has never been reloaded with new Co-60 sources. For STAAR to continue with its manufacturing and R&D efforts in the U.S., we need new Co-60 sources.

STAAR's two J.L Shepherd & Associates (JLS&A) Model 109-68 gamma irradiators for high dose work are covered under NRC License Number: CA 6299-30.

STAAR now have a contract in place with JLSB/A to provide new Co-60 sources and replace the existing, depleted sources for this irradiator. However, we have learned through JLS/A that the General Electric Model No. 1500 Package required to ship the new and de-commission the depleted sources to STAAR Surgical, CA is no longer certified for use.

If the new Co-60 sources cannot be shipped to STAAR in the near future, our ability to produce Collamer material and will be significantly impacted, which will endanger our ability to provide medical devices to patients in the U.S. and around the world, as well as keep our manufacturing and R&D teams in the U.S. working.

STAAR respectfully requests that the NRC consider a limited use of the GE model № 1500 Package in support of the STAAR Facility's High Dose Irradiator reload. These new sources are urgently and as we understand it, the alternative shipping method could create greater safety issues to the public, because it would require multiple transportation trips (rather than just one with the G.E. 1500 Package) thereby increasing the amount of time that these sources are on public roadways.

We greatly appreciate you're your attention and consideration of this important matter. If we can assist you in any way, please let us know.

Sincerely,

Alex Ossipov
Chief Chemist and RSO of STAAR SURGICAL

A handwritten signature in black ink, appearing to read 'Alex Ossipov', with a long horizontal flourish extending to the right.