Recommendation

The MDAC (**Dental**) deliberated the proposals on **08.08.2012** and recommended the following:

Agenda No.	File No.	Name of the Proposed Device	Recommendations
1.	29/Misc./14/ 2011-DC (11)	**"Easy-graft™ and Easy-graft™ CRYSTAL"**	The committee after deliberation recommended that the proposed study would be considered as Phase IV Clinical Study i.e. Post marketing Clinical Trial. Further based on the observations made after the review of the documents submitted by the firm the members recommended that the firm is required to submit the Information/Clarification on following points for taking further action in this regard :- **1.** Regulatory status of said study in other countries (including developed countries) and Justification to conduct of this first randomized study in India only. **2.** The ultimate benefit of the surgical procedure to the subjects **3.** Additional clinical benefits to the subjects from the study **4.** Additional clinical parameters such as FOV, absorbed dose of each exposure, etc., need to be added to protocol to address the safety and efficacy issues of the said study. Further cumulative dose of radiation for each patient

			and its safety may be ascertained as per the radiation guidelines in India. **5.** The biological sample to be sent out of the country for Histo-Metric Analysis should follow the Government of India guidelines of biological sample to be sent out of the country and an ethical justification would be warranted from ICMR or Institution Review Board. **6.** The financial implications of the study, comprising of details, such as payment to be made to the study subjects, the total amount of fund that would be paid by the company, for the proposed study, to the host institution, etc.