Recommendation:-

The MDAC (Orthopaedics) deliberated the proposals on **18.09.2012** and recommended the following:

Agenda No.	File No.	Name of the Proposed Device	Recommendations
1.	4-MD/CT-81/2012-DC	**"BST-CarGel®"**	The applicant has submitted one year Clinical Trial data of 80 patients, conducted outside India wherein 41 patients used "BST-CarGel®" and 39 patients undergone Microfracture Surgery. This device is CE marked and it can be marketed in EU. It is also available in Canada under Special Access programme. The committee is in the opinion that there is no adequate justification to waive-off the Clinical Trial in India. In view of above, the committees after deliberation recommended that Clinical trial need to be carried out in India after getting necessary permission from CDSCO. Marketing authorization approval may be considered after review of Clinical trial data generated on Indian Population.
2.	31-848-MD/2010-DC	**"AlloFuse DBM"**	The committee after deliberation recommended that Marketing authorization permission may be granted after submission of the following: 1. Clinical data 2. Adverse Event Details
3.	31-994-MD/2010-DC	**"OsseoFix-Spinal Fracture Reduction System"**	The committee after deliberation recommended that the marketing permission may be granted.
4.	31-188-MD/2006-Dc (Re-reg-2009) (End-05)	**"Vertebral Body Stenting System"**	The committee after deliberation recommended that the marketing permission may be granted.

Recommendation:-

The MDAC (Orthopaedics) deliberated the proposals on **22.03.2013** and recommended the following:

Agenda No.	File No.	Name of the Proposed Device	Recommendations
1.	4-MD/CT-81/2012-DC	**"BST-CarGel®"**	In response to earlier MDAC-Orthopaedics committee recommendations, the applicant made a request to waive-off the clinical trial requirement for approval of "BST-CarGel®". In today's meeting the committee after deliberation recommended that the applicant should submit published safety data of chitosan and long term evidence reports published in peer-reviewed journals. The committee may examine the above data after submission of the same by the applicant and final recommendations regarding waiver-off clinical trial may be considered.

Recommendations:-

The MDAC (Orthopaedics) deliberated the proposals on 06/08/2014 and recommended the following:-

Agenda No.	File No.	Name of the Firm & Name of the Proposed product	Recommendations
1.	**4-MD/CT-114/2014-DC**	**M/s. Mn Solutions** , Shop No. 26 & 27, IInd Floor, Prop no. WZ-26, Nangli Jalib Village, B-1, Janak Puri, New Delhi-110058. **Products:** **1. Cages** **2. Pedicular systems and Plates** **3. Corpectomy System** **4. Plate Cage** **5. Cervical Disc**	The committee has deliberated long term safety data presented by the firm and recommended that the permission may be granted for import into India.
2.	**4-MD/CT-115/2014-DC & 4-MD/CT-116/2014-DC**	**M/s. Heraeus Technologies India Pvt. Ltd.,** 370/20 GF-Shanti Nagar Near Rajiv Chowk, NH-8, Dist, Gurgaon. **Products:** **COPAL G +C & COPAL G +V**	The committee has deliberated the matter and recommended the firm to submit the following: 1. Documentary evidence showing whether the sensitivity test is required for the Clindamycin & Vancomycin in patients to rule out any systemic allergic reaction. 2. Detail of the Nature of complaints received w.r.t proposed products globally. 3. Reason for using antibiotics i.e. clindamycin, vancomycin with normal viscosity bone cement and not with low and high viscosity bone cement.

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			4. Published Data showing the drug- drug interaction of gentamycin with clindamycin \ vancomycin. 5. Documentary proof of the heat sensitivity\stability of clindamycin and vancomycin while using with the bone cement. 6. Published data regarding longevity of bone cement with these antibiotics. The same would be presented before this committee for further review.
3.	**31-1008-MD/2011-DC**	**M/s. Stryker India Pvt. Ltd.**, C-5, SDA Commercial Complex, New Delhi-110016 **Products: MEDPOR (Orthopaedic Implant)**	The committee has deliberated the matter and recommended that the products i.e. Medpor TITAN, Medpor and Medpore coated tear drain may be considered for registration. However the firm failed to provide complete information for the remaining two products i.e. Medpor Plus & Medpor contain.
4.	**CLAA/MD/ORISSA/01/2008-DC**	**M/s.I.F.G.L Refractories Ltd., Sector-A, Kalunga Industrial Estate, P.O. Kalunga – 770031.** **Products: BioGraft HABG Active Ortho:**	The committee has deliberated the matter and recommended that firm needs to conduct phase III multicentric clinical trial in India in humans in statistically significant patients geographically with minimum follow up of 2 years. The firm is required to submit the protocol before this meeting for review..

S.No.	Name & Designation of MDAC (Orthopaedics) Experts	Signatures
1.	**Dr. Shishir Rastogi,** Professor of Orthopaedics, Dept. of Orthopedics, AIIMS, New Delhi.	

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2.	**Dr. V.K. Goyal,** Chief Specialist of Orthopaedics, Deen Dayal Upadhyay Hospital, New Delhi	
3.	**Dr. R.K. Arya,** Prof and Head, Dept. of Orthopaedics, Ram Manohar Lohia Hospital, Delhi	6/8/14