

## Recommendation:-

The MDAC (orthopaedic) deliberated the proposals on 04.10.2013 and recommended the following:-

<b>Agenda No.</b>	<b>File No.</b>	<b>Name of the Firm&amp; Name of the Proposed product</b>	<b>Recommendations</b>
1.	<b>31-1159-MD/2012-DC</b>	<b>M/s Mn solutions, New Delhi has applied for registration of following products</b> 1. Cages 2. Pedicular Systems and Plates 3. Corpectomy system 4. Plate cage 5. Cervical disc	The firm has demonstrated with a samples difference between the existing and proposed devices. It is observed that the proposed devices are similar with already approved device. The committee after deliberation recommended that the renewal of registration certificate for the proposed product may be considered with the conditions to submit the published long term safety data in indexed journals the published data shall be circulated to the experts for their comments
2.	<b>4-MD/CT-92/2013-DC</b>	M/s Karmic Labs Pvt. Ltd Mumbai has applied for the grant of permissions to conduct the pilot Global Clinical Trial “evaluation of the Agili-C Bi-phasic Implant	The committee recommended that firm is required to submit the feasibility of the T2 mapping in MRI and Staining Dye (Safranin O/ Toluidine -Blue) in India, which may be forwarded to the experts for their comments before grant of the permission to conduct Global Clinical trial

3.	<b>4-MD/CT-97/2013-DC</b>	M/s Meril Life Sciences India Pvt Ltd., Mumbai has applied for conducting the Phase-IV Clinical Trial Study of the product i.e Freedom Total Knee system. The said product is already approved for marketing in country.	<p>The proposal was deliberated by MDAC – Orthopedic in its meeting held on 04.10.2013 and recommended that the firm is required to submit the following documents :-</p> <ol style="list-style-type: none"> <li>1. Justification of the sample size.</li> <li>2. Geographical distribution of the sites and 50 % should be from Government Hospital.</li> <li>3. Patient Information sheet mentioning the clause for the supply of the device free of cost and compensation in case of injury/deaths as per Drugs and Cosmetics Act &amp; Rules.</li> <li>4. Undertaking from the sponsor that they will provide the device free of cost during the trail.</li> <li>5. Ethics committee approval</li> </ol> <p>After submission of the documents permission may be granted</p>
4.	<b>CLAA/MD/ORISSA/01/2008-DC</b>	<p>M/s I.F.G.L Refractories Ltd., Kalunga has applied for the manufacturing of following product under the categories of Orthopaedic implant</p> <ol style="list-style-type: none"> <li>1. BioGraft HA New Ortho:</li> <li>2. BioGraft HABG Active Ortho:</li> </ol>	<p>The committee after delbartion recommended that for the product Biograft HABG Active Ortho the firm is required to submit published long term safety data in indexed journals.</p> <p>For the product Biograft HA new ortho intended for orthopedic use permission may be granted</p>

