

Products Approved in FY 2015: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Sep. 18, 2015	TEMCELL HS Inj. (JCR Pharmaceuticals Co., Ltd.)	Approval	Human somatic stem cell-processed products	Human (allogeneic) bone marrow-derived mesenchymal stem cell	A human (allogeneic) bone marrow-derived mesenchymal stem cell that can be obtained by expanding and culturing the nucleated cell isolated from the bone marrow aspirate of healthy adult donor. The product is administered via intravenous infusion to treat acute graft-versus-host disease (acute GVHD) after allogeneic hematopoietic stem cell transplantation. [Orphan regenerative medical products]
Regenerative Medical Products	Sep. 18, 2015	HeartSheet (Terumo Corporation)	Conditional/Time-limited Approval	Human somatic stem cell-processed products	Human (autologous) skeletal myoblast-derived cell sheet	A human (autologous) skeletal myoblast-derived cell product consisting of the patient's skeletal myoblast that has been cultured, proliferated, and cryopreserved as a main component, and the instruments, etc. for shaping the cell sheets in medical institutions as sub-components. The product is used for treating serious heart failure caused by ischemic heart disease by applying the sheet-shaped cells to the surface of the heart during the open chest surgery when standard therapies are not sufficiently effective.