

Products Approved in FY 2016: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company, Corporate No.)	New Approval/Parti al Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Sep. 29, 2016	JACE (Japan Tissue Engineering Co., Ltd.)	Change	Human somatic cell- processed product	Human (autologous) epidermis-derived cell sheet	<p>A product consisting of human (autologous) epidermis-derived cell sheet, which is produced using Green's technique, packaged in a primary container (main component), and a container (filled with tissue transport fluid) for transporting the patient's skin tissue to the manufacturing site (sub-component).</p> <p>To prepare the cell sheet, epidermal cells derived from a postage-stamp-sized piece of skin taken from the patient's own healthy skin tissue are co-cultured with mouse embryo-derived 3T3-J2 feeder cells and formed into a sheet. The cell sheet is released in the state of being immersed in preservative liquid. The product has already been approved for an indication for cases of serious and extensive burns where sufficient donor skin sites for autologous skin grafts are not available, and at the same time, where the total area of deep dermal and full-thickness burns accounts for 30% or more of the total body surface area (Approval No. 21900BZZ00039000).</p> <p>The application was submitted for an additional indication for the treatment of "giant congenital melanocytic nevus" (A "partial change" application). The results from domestic clinical studies in which the product was grafted to cover the site of excised melanocytic nevus were submitted to evaluate the efficacy and safety of the product.</p>