| Current as of the date May 25, 2015 | | | | | | | | | | | | | |
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| 1993 | 1993/11/15 | (5gu B) No. 1 | | Implantable defibrillator | Patients at high risk of sudden death due to ventricular tachyarrhythmia | Medtronic Japan Co., Ltd. | Patients at high risk of sudden death from ventricular tachyarrhythmias | Medtronic Japan Co., Ltd. | 1994/7/7 | PCD 7217 implantable | | | Approved |
| 1993 | 1993/11/15 | (5gu B) No. 2 | | Adsorption type blood purifier | Patients with advanced dialysis-related amyloidosis (DRA) resulting in significant restrictions in daily life due to severe mobility impairment | Kanegafuchi Chemical Industrial Co., Ltd. | Patients with advanced dialysis-related amyloidosis (DRA) resulting in significant restrictions in daily life due to severe mobility impairment | Kaneka Corporation | 1994/4/8 | Lixelle | | | Approved |
| 1995 | 1995/4/1 | (7gu A) No. 3 | 3 | Magnetic cell separation system | Separation and isolation of hematopoietic stem cells (CD34-positive cells) during allogeneic or autologous bone marrow transplantation or autologous peripheral blood stem cell transplantation. | Baxter | Separation and isolation of hematopoietic stem cells (CD34-positive cells) during autologous bone marrow or peripheral blood stem cell transplantation in patients with malignant tumors | Takara Bio, Inc. | 2001/8/31 | Isolex 300 | This device is currently not being supplied. | | Approved |
| 1995 | 1995/4/1 | (7gu A) No. 4 | 2 | Lymphocyte isolation equipment | Elimination of T lymphocytes for allogeneic bone marrow transplantation | Asahi Medical Co., Ltd. | - | - | - | - | Designation revoked (1999/05/27) | 1999/5/27 | Revoked |
| 1996 | 1996/4/1 | (8gu A) No. 5 | 3 | Partially disposable pump system for pain relief | Alleviation of severe pain associated with various types of cancer for which oral administration, intravenous injection or subcutaneous injection of narcotics is not expected to be sufficiently effective | Terumo Corp | - | - | - | - | Designation revoked (2001/08/24) | 2001/8/24 | Revoked |
| 1999 | 1999/5/27 | (11gu) No. 6 | | Implantable ventricular assist device | Improvement of cardiac function or systemic condition, including prevention or improvement of dysfunction of various organs secondary to heart failure and reduction of the number or dosage of drugs used prior to surgery in patients with end-stage heart failure, including those with acute myocarditis which led to dilated cardiomyopathy, ischemic heart disease, acquired valvular disease or chronic heart failure, and patients with other types of cardiogenic circulatory failure who developed severe heart failure while waiting for heart transplantation or require long-term circulatory support, for whom survival is difficult even with assisted circulation and maximal medical therapy approved in Japan | Nissho Co., Ltd. | Improvement of circulation in patients with severe heart failure with persisting decompensation after failing conventional treatments (drug therapy and existing assisted circulation) for whom survival is difficult without heart transplantation | Nipro Corporation | 2009/11/18 | HeartMate XVE implantable left ventricular assist system | | | Approved |
| 1999 | 1999/8/25 | (11gu) No. 7 | | Implantable ventricular assist device | Long-term maintenance of blood circulation, including as a bridge to heart transplantation, for patients with severe irreversible end-stage heart failure at risk of death due to decreased cardiac function | Baxter | Improvement of circulation in patients with severe heart failure with persisting decompensation after failing conventional treatments (drug therapy and existing assisted circulation) for whom survival is difficult without heart transplantation | Edwards Lifesciences Corporation | 2001/8/31 | Novacor left ventricular assist system | Designation revoked (2013/5/14) | 2013/5/14 | Approved |

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| 2000 | 2000/6/16 | (12gu) No. 8 | 5 | Magnetic cell separation system | Separation and isolation of hematopoietic stem cells (CD34-positive cells) during allogeneic bone marrow or peripheral blood stem cell transplantation, autologous bone marrow or peripheral blood stem cell transplantation or umbilical cord blood transplantation for the treatment of malignant tumors, non-neoplastic disease, congenital disease or severe autoimmune disease | Kirin Brewery Company, Limited | - | - | - | - | Designation revoked (2006/12/21) | 2006/12/21 | Revoked |
| 2001 | 2001/4/23 | (13gu) No. 9 | 3 | Adsorption type blood purifier | Induction of remission in patients with active Crohn's disease | Japan Immunoresearch Laboratories Co., LTD | Induction of remission in patients with moderate to severe active Crohn's disease experiencing clinical symptoms caused by pathological changes in the large intestine where nutritional therapy and existing drug therapies are ineffective or cannot be used | JIMRO Co., Ltd. | 2008/9/2 | Adacolumn | | | Approved |
| 2001 | 2001/8/1 | (13gu) No. 10 | | Programmable implantable pump for continuous infusion | Cerebral (infantile) palsy, spinal cord vascular disorders, cervical spondylosis, posterior longitudinal ligament ossification, multiple sclerosis, spinocerebellar degeneration (hereditary spastic paraplegia), or severe spastic paralysis due to traumatic sequelae (spinal cord injury or head trauma) | Medtronic Japan Co., Ltd. | A pump for intrathecal administration of baclofen for intrathecal injection in patients with severe spastic paralysis resulting from cerebrospinal diseases (limited to cases where existing treatments are not sufficiently effective) . This product is intended for adults (17 years or older). | Medtronic Japan Co., Ltd. | 2005/3/25 | SynchroMed EL pump | | | Approved |
| 2005 | 2005/10/14 | (17ki) No. 11 | | Purifier for the removal of blood cells | Inhibition of ocular symptoms in patients with Behcet's disease with refractory uveoretinitis | JIMRO Co., Ltd. | - | - | - | - | | | |
| 2005 | 2005/12/9 | (17ki) No. 12 | | Prosthesis promoting intravascular embolization in the central circulation | Prevention of protrusion and derailment of a coil mass into the parent artery during coil embolization surgery for patients with wide-neck cerebral aneurysms (neck width ≥ 4 mm or dome-to-neck ratio < 2) among those with unruptured cerebral aneurysms (maximum diameter ≥10 mm) that are difficult to treat with surgical intervention (e.g. clipping) or with coil embolic therapy using embolic coils alone | Johnson & Johnson K.K. | Prevention of protrusion and derailment of a coil mass into the parent artery during coil embolization surgery for patients with unruptured cerebral aneurysms of ≥7 mm in maximum diameter on parent arteries of 2.5 to 4 mm in diameter among those with wide-neck cerebral aneurysms (neck width ≥ 4 mm or dome-to-neck ratio < 2) that are difficult to treat with surgical intervention (e.g. clipping) or with coil embolic therapy using embolic coils alone | Johnson & Johnson K.K. | 2010/1/8 | Codman Enterprise vascular reconstruction device (VRD) | | | Approved |
| 2007 | 2007/7/6 | (19ki) No. 13 | 2 | Implantable ventricular assist system | Improvement and maintenance of blood circulation in patients with irreversible end-stage heart failure with dilated cardiomyopathy or ischemic heart disease for whom heart transplantation is indicated and who have no chance of recovery with conventional medical therapies (drug therapy or intra-aortic balloon pump for assisted circulation) at imminent risk of death due to decreased cardiac function | Sun Medical Technology Research Corp. | Improvement of circulation for the period prior to heart transplantation in patients with severe heart failure for which heart transplantation is indicated and who have persisting decompensation despite drug therapy or circulatory assist devices such as an external ventricular assist device and for whom survival is difficult without heart transplantation | Sun Medical Technology Research Corp. | 2010/12/8 | Evaheart left ventricular assist system | | | Approved |

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| 2008 | 2008/6/11 | (20ki) No. 14 | | Prosthesis promoting intravascular embolization in the central circulation | Prevention of protrusion and derailment of a coil mass into the parent artery during coil embolization surgery for patients with wide-neck cerebral aneurysms (neck width ≥ 4 mm or dome-to-neck ratio < 2) among those with unruptured cerebral aneurysms (maximum diameter ≥10 mm) that are difficult to treat with surgical intervention (e.g. clipping) or with coil embolic therapy using embolic coils alone | Boston Scientific Corporation | – | – | – | – | Designation revoked (2011/12/09) | 2011/12/9 | Revoked |
| 2008 | 2008/6/11 | (20ki) No. 15 | 2 | Non-autologous cell cultured corneal epithelial cell | Repair of corneal epithelium or improvement of visual function of patients with symptoms of corneal epithelial cell dystrophy | ArBlast Co., Ltd. | – | – | – | – | | | |
| 2008 | 2008/12/15 | (20ki) No. 16 | 1 | Semiconductor laser for photodynamic therapy (PDT) | Used in combination with the light-sensitive substance talaporfin sodium for the treatment of malignant glioma | Panasonic Shikoku Electronics Co., Ltd. (Currently, Panasonic Healthcare Co., Ltd.) | – | – | – | – | Designation revoked (2013/09/19) Designation was transferred to (25ki) No. 24 with a change in the anticipated intended use or indication from malignant glioma to malignant brain tumor (expansion of range) | 2013/9/19 | Revoked |
| 2008 | 2008/12/15 | (20ki) No. 17 | 2 | Implantable ventricular assist system | Used as a bridge to heart transplantation in patients with end-stage severe heart failure who meet the criteria for heart transplantation and who are at imminent risk of death due to decreased cardiac function | Century Medical, Inc. | Improvement of circulation for the period prior to heart transplantation in patients with severe heart failure for which heart transplantation is indicated and who have persisting decompensation despite drug therapy or circulatory assist devices such as an external ventricular assist device and for whom survival is difficult unless without heart transplantation | Century Medical, Inc. | 2013/11/22 | Jarvik2000 Implantable ventricular assist system | | | Approved |
| 2008 | 2009/3/11 | (21ki) No. 18 | | Implantable ventricular assist system | Improvement of circulation in patients with end-stage heart failure who require heart transplantation. | Terumo Corp | Improvement of circulation for the period prior to heart transplantation in patients with severe heart failure for which heart transplantation is indicated and who have persisting decompensation despite drug therapy or circulatory assist devices such as an external ventricular assist device and for whom survival is difficult unless without heart transplantation | Terumo Corporation | 2010/12/8 | DuraHeart left ventricular assist system | | | Approved |

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| 2009 | 2009/7/7 | (21ki) No. 19 | 3 | Purifier for the removal of blood cells | Improvement of clinical symptoms in patients with pustular psoriasis | JIMRO Co., Ltd. | Used for improvement of clinical symptoms of moderate or severe pustular psoriasis for which existing oral therapies are ineffective or cannot be used in systemic treatment | JIMRO Co., Ltd. | 2012/6/25 | Adacolumn | | | Approved |
| 2009 | 2009/10/28 | (21ki) No. 20 | 3 | Endobronchial loading material | Treatment of secondary refractory pneumothorax or bronchial fistula where surgery is difficult | Harada Corporation | Loading into bronchi for the purpose of closing a fistula in patients with secondary refractory pneumothorax, air leak persisting after pneumonectomy or other fistulae which are difficult to treat with surgery and for whom bronchial occlusion is indicated | Harada Corporation | 2013/1/28 | Endobronchial Watanabe Spigot (EWS) | | | Approved |
| 2009 | 2010/3/19 | (22ki) No. 21 | 1 | Fetal shunt | Placement into the fetal chest cavity and the maternal amniotic fluid cavity in order to continuously drain the pleural effusion accumulating in the fetal thoracic cavity into the amniotic sac, thereby improving hydrops fetalis, preventing pulmonary hypoplasia and prolonging pregnancy | Hakko Co., Ltd. | Continuous drainage of pleural effusion into amniotic fluid cavity in cases of fetal pleural effusion when thoracocentesis has failed | Hakko Co., Ltd. | 2011/12/20 | Fetal shunt | | | Approved |
| 2010 | 2011/3/18 | (23ki) No. 22 | 3 | Human tissue for autologous transplantation | Rapid epithelialization of refractory erosions and ulcers in patients with epidermolysis bullosa | Japan Tissue Engineering Co., Ltd. | – | – | – | – | | | |
| 2011 | 2011/6/17 | (23ki) No. 23 | 3 | Pump for external ventricular assist device | Improvement of circulation before heart transplantation or restoration of cardiac function in pediatric patients (with body surface area ≤ 1.5 $m^2$ and body weight between 2 kg and 60 kg) with severe heart failure whose symptoms do not improve with conventional medication or assisted circulation | Cardio, Inc. | – | – | – | – | | | |
| 2013 | 2013/9/19 | (25ki) No. 24 | 1 | Semiconductor laser for photodynamic therapy (PDT) | Use in combination with the light-sensitive substance talaporfin sodium for the treatment of malignant brain tumors | Panasonic Healthcare Co., Ltd. | Use in photodynamic therapy (PDT) with the light-sensitive substance talaporfin sodium<br>Target disease: primary malignant brain tumors (limited to cases treated with surgical resection) | Panasonic Healthcare Co., Ltd. | 2013/9/20 | PD Laser BT | Designation was transferred from (20ki) No. 16 with the change in anticipated intended use or indication from malignant glioma to malignant brain tumor | | Approved |
| 2014 | 2014/9/17 | (26ki) No. 25 | | Semiconductor laser for photodynamic therapy (PDT) | Local failure after chemoradiotherapy or radiotherapy for esophageal cancer | Panasonic Healthcare Co., Ltd. | – | – | – | – | | | |
| 2014 | 2014/11/25 | (26sai) No. 1 | | Cultured human (autologous) epidermal cell sheet | Rapid epithelialization of lesions removed nevi in patients with giant congenital melanocytic nevi | Japan Tissue Engineering Co., Ltd. | – | – | – | – | | | |

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| 2014 | 2014/12/19 | (26ki) No. 26 | | HAl for medical use (lower limb type) | Inhibition of progression of muscular atrophy and muscle weakness, in patients with indolent or chronic progressive neuromuscular intractable diseases , by supporting for muscle contraction after wearing the HAL on a regular and intermittent basis | CYBERDYNE Inc | - | - | - | - | | | |
| 2014 | 2014/12/19 | (26ki) No. 27 | | Tear exchangeable limbal supported rigid contact lens | Correction of visual acuity and improvement of symptoms in patients with ocular sequelae caused by erythema exsudativum multiforme major (stevens-Johnson syndrome, toxic epidermal necrolysis) | SUN CONTACT LENS Co., Ltd. | - | - | - | - | | | |
| 2014 | 2015/3/25 | (27sai) No. 2 | | EYE-01M | Corneal epithelial stem cell deficiency | Japan Tissue Engineering Co., Ltd. | - | - | - | - | | | |