Class 1 Device Recall Pipeline Embolization Device

See Related Information 22

Date Initiated by Firm	October 05, 2016
Create Date	November 09, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0307-2017
Recall Event ID	75358[23]
PMA Number	P100018[24]
Product Classification	Intracranial aneurysm flow diverter[25] - **Product Code** OUT[26]
Product	Pipeline Embolization Device (Pipeline Classic) The device is indicated for the endovascular treatment of adults (22 year of age or older) with large or giant widenecked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segements.
Code Information	65, A110203, A122033, A133605, A139226, A150201, A066694, A080852, A096669, A110206, A122035, A133606, A139227, A150202, A066695, A080853, A096670, A110207, A123930, A133607, A139229, A150203, A066696, A080854, A096671, A110208, A123931, A134224, A139853, A150204, A069628, A080855, A096673, A110209, A123932, A134225, A139854, A150205, A069630, A081550, A096675, A110210, A123933, A134226, A139864, A150894, A069631, A081551, A098120, A113417, A123935, A134227, A139867, A150898, A150899, A162848, A185769, A225554, A261101, A297968, A317168, A015452, A150900, A162850, A185771, A225555, A261102, A297970, A317171, A017863, A150901, A162851, A185772, A226043, A261106, A297971, A317937, A019067, A150902, A162853, A185773, A226051, A261109, A297973, A317940, A019687, A151239, A162854, A188190, A227129, A263738, A300193, A318732, A019498, A151240, A162855, A188195, A229179, A265492, A300194, A319040, A019689, A151241, A164383, A190077, A232637, A266994, A300991, A319043, A019686, A151242, A164384, A190079, A232638, A266997, A300992, A319130, A019688, A151243, A164385, A190080, A232640, A266999, A300993, A320823, A020051, A151244, A165179, A190081, A234756, A267000, A302644, A320826, A020185, A151245, A165180, A190082, A238664, A267001, A302645, A320827, A020487, A151246, A166121, A193900, A238666, A269767, A302646, A322378, A020486, A151248, A166122, A193902, A238667, A269771, A304830, A322381, A020485, A152139, A166123, A193904, A239875, A269773, A304842, A322384, A020484, A152140, A167455, A193905, A239877, A269774, A304844, A327069, A020184, A152141, A167457, A193906, A241057, A269775, A304846, 9961450, A020035, A152142, A169229, A197312, A242547, A271509, A304847, 9961902, A020047, A152143, A169230, A197314, A242548, A272748, A306243, 9961900, A020910, A153769, A169231, A199979, A242550, A272750, A306245, 9961899, A021481, A153770, A171151, A199983, A242559, A272752, A306251, 9962409, A021690, A153771, A171156, A204514, A242561, A274216, A306253, 9962411, A021689, A153772, A171163, A204515, A245762, A274223, A306254, 9962666, A022709, A153773, A171165, A204516, A245765, A276038, A306256, 9962420, A022520, A154448, A171168, A211767, A245767, A276041, A307932, 9962984, A022522, A154450, A171248, A211769, A245768, A278715, A307935, 9963258, A022519, A154452, A174423, A214097, A245770, A278718, A307940, 9963003, A024283, A154453, A174424, A214779, A245771, A281388, A307941, 9963797, A024276, A154454, A174426, A214781, A249221, A281389, A309598, 9963255, A023270, A156152, A174427, A214782, A249225, A281390, A309599, 9963792, A024213, A156157, A174428, A214783, A250673, A283037, A309601, 9962996, A021046, A157201, A174430, A214784, A250675, A283040, A309603, 9964272, A029219, A157202, A174432, A215491, A252980,

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Recalling Firm/ Manufacturer	Micro Therapeutics Inc, Dba Ev3 Neurovascular 9775 Toledo Way Irvine CA 92618-1811
For Additional Information Contact	949-837-3700
Manufacturer Reason for Recall	Delamination and detachment of the PTFE (polytetrafluoroethylene) coating material may lead to PTFE coating in the blood stream.
FDA Determined Cause [2]	Device Design
Action	Medtronic sent an Urgent Medical Device Recall letter dated October 5, 2016, to all affected customers to inform them that Medtronic has identified the potential for an issue with a specific set of lot numbers of Medtronic Neurovascular products as noted where the PTFE (polytetrafluoroethylene) coating could delaminate and separate from the delivery wire. Customers are instructed to complete the attached customer confirmation certificate and fax it to Medtronic at (949) 434-5020 to the attention of Neurovascular Quality. On October 14, 2016, Medtronic announced that it has notified customers of a voluntary recall of certain lots of its Pipeline embolization device, Alligator retrieval device and X-Celerator hydrophilic guidewire. The recall also includes the stylet containing UltraFlow flow directed micro catheters and Marathon flow directed micro catheters. This voluntary recall is being conducted due to the potential separation and detachment of the polytetrafluoroethylene (PTFE) coating on parts of these devices. Should the PTFE separate from the delivery wire or stylets, PTFE particulate could enter the blood stream of the patient. PTFE in the blood stream, based on the size and quantity, could lead to a thromboembolic event. Customers were asked to complete the attached Customer Confirmation Certificate and fax it to Medtronic at 1-949-434-5020 to the attention of Neurovascular Quality. Customers with questions were instructed to contact their Medtronic representative.
Quantity in Commerce	84,278 units total (17,811 in US)
Distribution	Worldwide Distribution - US (nationwide) and Internationally to Argentina, Australia, Austria, Bahrain, Bangladesh, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, Finland, France, Germany, Greece, Hong Kong, Hungary, Iran, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Malaysia, Mexico, Nepal, Netherlands, Nicaragua, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Puerto Rico, Russian Federation, Saudi Arabia, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, Uruguay, Venezuela, and Vietnam.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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