

[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵**Class 2 Device Recall Ingenia**[510\(k\)](#)⁷ [DeNovo](#)⁸ [Registration & Listing](#)⁹ [Adverse Events](#)¹⁰ [Recalls](#)¹¹ [PMA](#)¹² [HDE](#)¹³ [Classification](#)¹⁴ [Standards](#)¹⁵
[CFR Title 21](#)¹⁶ [Radiation-Emitting Products](#)¹⁷ [X-Ray Assembler](#)¹⁸ [Medsun Reports](#)¹⁹ [CLIA](#)²⁰ [TPLC](#)²¹[New Search](#)[Back to Search Results](#)**Class 2 Device Recall Ingenia**

Date Initiated by Firm	August 28, 2026
Date Posted	September 25, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3311-2026
Recall Event ID	99834 ²³
510(K)Number	K193215 ²⁴ K213516 ²⁵ K223458 ²⁶ K230972 ²⁷ K251397 ²⁸ K251808 ²⁹
Product Classification	System, nuclear magnetic resonance imaging ³⁰ - Product Code LNH ³¹
Product	Ingenia Elition S and Ingenia Elition X; Model number (REF): 1. 781357 (S), 2. 782106 (S), 3. 782137 (S), 4. 782157 (S), 5. 781358 (X), 6. 782107 (X), 7. 782119 (X), 8. 782136 (X), 9. 782158 (X), 10. 782198 (X); Software Versions: R11, R12 and R13;
Code Information	1. Model number (REF): 781357 (S); UDI-DI: 00884838088108; Serial Numbers: 46002, 46012, 46013, 46017, 46018, 46020, 46021, 46023, 46025, 46027, 46029, 46036, 46039, 46041, 46042, 46044, 46053, 46054, 46082, 46086, 46092; 2. Model Number (REF): 782106 (S); UDI-DI: 00884838098329; Serial Numbers: 46203, 46204, 46207, 46208, 46209, 46219, 46220, 46225, 46235, 46243, 46249, 46258, 46269, 46270, 46286, 46302, 46315, 46325, 46375; 3. Model Number (REF): 782137 (S); UDI-DI: 00884838108615; Serial Numbers: 64001, 64002, 64003, 64004, 64005, 64014, 64015, 64029, 64032, 64039, 64040, 64041, 64042, 64049, 64050, 64051, 64052; 4. Model Number (REF): 782157 (S); UDI-DI: 00884838115682; Serial Numbers: 8900, 89003; 5. Model Number (REF): 781358 (X); UDI-DI: 00884838088115; Serial Numbers: 45008, 45009, 45010, 45011, 45024, 45026, 45028, 45029, 45032, 45033, 45034, 45035, 45036, 45037, 45040, 45041, 45046, 45048, 45049, 45054, 45055, 45056, 45060, 45062, 45066, 45070, 45072, 45073, 45075, 45076, 45078, 45086, 45087, 45089, 45090, 45091, 45093, 45094, 45096, 45097, 45098, 45099, 45100, 45105, 45108, 45112, 45113, 45115, 45116, 45119, 45120, 45127, 45129, 45132, 45136, 45138, 45140, 45146, 45147, 45148, 45152, 45154, 45156, 45157, 45160, 45162, 45168, 45174, 45181, 45186, 45187, 45189, 45190, 45191, 45194, 45205, 45215, 45231, 45235, 45237, 45243, 45245, 45246, 45250, 45252, 45264, 45272, 45277, 45278, 45290, 45296, 45316, 45317, 45319, 45323, 45328, 45333, 45335, 45340, 45342, 45374, 45379, 45395, 45398, 45399, 45406, 45407, 45414, 45423, 45441; 6. Model Number (REF): 782107 (X); UDI-DI: 00884838098336; Serial Numbers: 45500, 45503, 45506, 45507, 45508, 45509, 45510, 45514, 45519, 45523, 45525, 45530, 45532, 45533, 45534, 45536, 45542, 45545, 45547, 45551, 45560, 45561, 45573, 45574, 45578, 45579, 45589, 45594, 62019, 62024, 62026, 62030, 62031, 62033, 62035, 62037, 62040, 62041, 62048, 62051, 62052, 62056, 62058, 62059, 62061, 62062, 62063, 62065, 62067, 62070, 62071, 62073, 62080,

62081, 62082, 62088, 62092, 62098, 62134, 62136, 62137, 62148, 62151, 62152, 62153, 62159, 62178, 62181, 62182, 62197;

7. Model Number (REF): 782119 (X);
UDI-DI: 00884838104129;
Serial Number: 66001;

8. Model Number (REF): 782136 (X);
UDI-DI: 00884838108608;
Serial Numbers: 28500, 28502, 28503, 28504, 28506, 28507, 28509, 28510, 28514, 28515, 28516, 28521, 28524, 28525, 28526, 28527, 28528, 28529, 28532, 28533, 28535, 28536, 28538, 28540, 28542, 28543, 28544, 28546, 28547, 28548, 28549, 28550, 28555, 28558, 28559, 28560, 28563, 28564, 28565, 28566, 28568, 28572, 28573, 28576, 28577, 28579, 28581, 28583, 28585, 28586, 28587, 28591, 28592, 28593, 28594, 28595, 28596, 28597, 28598, 28599, 28604, 28605, 28608, 28611, 28612, 28613, 28614, 28615, 28616, 28618, 28619, 28623, 28625, 28628, 28629, 28630, 28631, 28632, 28635, 28636, 28638;

9. Model Number (REF): 782158 (X);
UDI-DI: 00884838115699;
Serial Numbers: 90001, 90002, 90004, 90006, 90007, 90010, 90011, 90015, 90016, 90017, 90018, 90023, 90024, 90027, 90036;

10. Model Number (REF): 782198 (X);
UDI-DI: 00884838128460;
Serial Numbers: 57003, 57004, 57005, 57009;

FEI Number	3006648320
Recalling Firm/ Manufacturer	Philips North America 222 Jacobs St Cambridge MA 02141-2296
For Additional Information Contact	800-722-9377
Manufacturer Reason for Recall	When exporting diffusion tensor imaging (DTI) scans from a MR system using the Enhanced MR DICOM format, the exports contain incorrect data (diffusion directions). If the Enhanced MR DICOM export is used in conjunction with third-party software for tractography (e.g. for mapping nerve fiber pathways in the brain), the software will not be able to correctly process the DTI data for reconstruction.
FDA Determined Cause ²	Software design
Action	On August 28, 2026, URGENT Medical Device Correction letters were sent to customers. Actions to be taken: 1. To prevent the issue from occurring while Philips is developing the software solution, use the Classic DICOM transfer option for exporting DTI scans. 2. You may continue to use your system(s) in accordance with the intended use. 3. Circulate this notice to all users of this device so that they are aware of the issue and associated hazard/harm. 4. Please retain this Urgent Medical Device Correction letter with your system(s) until the software upgrade is installed; ensure the notice is in a place likely to be seen/viewed.
Quantity in Commerce	340
Distribution	Worldwide distribution - Nationwide and the countries of Algeria, Argentina, Australia, Austria, Bangladesh, Belgium, Brazil, Canada, Chile, China, Colombia, Cyprus, Czech Republic, Denmark, Dominican Rep, Ecuador, Egypt, Equator. Guinea, Finland, France, French Guiana, Georgia, Germany, Ghana, Greece, Honduras, Hong Kong, Hungary, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Latvia, Lebanon, Luxembourg, Malaysia, Malta, Martinique, Mauritius, Mexico, Moldova, Monaco, Morocco, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Norway, Pakistan, Palestine, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Fed., Saudi Arabia, Serbia, Singapore, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Syria, Taiwan, Thailand, Tunisia, Türkiye, United Kingdom, Uruguay, Utd.Arab.Emir., Uzbekistan, Vietnam.
Total Product Life Cycle	TPLC Device Report ³²

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](#)³³.

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.

510(K) Database

[510\(K\)s with Product Code = LNH](#)³⁴

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