FDA SOFTWARE DOCUMENTATION LEVEL · JUNE 2023 FINAL GUIDANCE AUDIT

Enhanced vs. Basic Documentation Level in AI/ML SaMD

Under FDA's June 14, 2023 guidance, **Enhanced Documentation** applies only where a software failure presents a hazardous situation with a **probable risk of death or serious injury** (excluding **purely hypothetical risks**) prior to risk controls; **Basic Documentation** applies otherwise. Across 687 post-guidance AI/ML SaMD authorizations, 107 name a 2023 level: **74.8% cleared at Basic**, and Enhanced clusters in five categories rather than AI or De Novo status.

74.8%
All AI/ML SaMD Basic
80 Basic vs. 27 Enhanced (n=107 naming a level)

95.0%
Radiology CADe/CADx/CADt
19 Basic vs. 1 Enhanced (QAS/QFM/QDQ/QBS/MYN/POK)

81.3%
AI/ML SaMD With PCCP
13 Basic vs. 3 Enhanced (PCCP does not force Enhanced)

66.7%
AI/ML SaMD De Novos
4 Basic vs. 2 Enhanced (2 of 2 Radiology De Novos Basic)

DOCUMENTATION LEVEL BY COHORT (N=107)

Basic Enhanced

SEGMENT (JUN 14, 2023 TO NOV 15, 2026)	B / E	% BASIC	SPLIT
All AI/ML SaMD naming a level	80 / 27	**74.8%**	
Radiology (RA), all codes	56 / 16	77.8%	
Radiology, excl. RT contouring	56 / 9	**86.2%**	
Radiology CADe / CADx / CADt	19 / 1	**95.0%**	
AI/ML SaMD with PCCP	13 / 3	81.3%	
AI/ML SaMD De Novos (all panels)	4 / 2	66.7%	
Anesthesiology / Acoustic / Sleep (AN)	9 / 0	100.0%	
Cardiovascular (CV)	3 / 6	33.3%	
Radiology RT Contouring (QKB / MUJ)	0 / 7	0.0%	
Autonomous Retinal AI (OP / PIB)	0 / 2	0.0%	

ILLUSTRATIVE BASIC DOCUMENTATION PRECEDENTS

Radiology CADe/CADx/CADt (19 of 20 Basic): Chest X-ray CADe with PCCP **K252486 (Sep 2026)**, multi-finding chest CADx **K261378 (Aug 2026)**, chest triage **K253751 (Jul 2026)** & **K231871 (Jan 2024)**, lung screening CADe/CADx **K251474 (Feb 2026)**, mammography CADe/CADx **K260898 (Aug 2026)** & **K243341 (Jul 2025)**, ICH stroke triage **K242292 (Sep 2024)**, and ultrasound CADx **K261679 (Oct 2026)**.

AI/ML SaMD De Novos (4 of 6 Basic; 2 of 2 Radiology): Breast risk prediction **DEN240047, Allix5 (May 2025)**, opportunistic bone density **DEN230023, Rho (Apr 2024)**, prostate pathology prognosis with PCCP **DEN240068, ArteraAI (Jul 2025)**, and pediatric otoscopy **DEN250014, Tyto (Mar 2026)**.

PCCPs & Consumer/Clinical Monitoring (Basic): Digital pathology breast prognosis **K254115 (May 2026)**, hypertension notification **K250507 (Sep 2025)**, sleep apnea notification **K240929 (Sep 2024)**, and loss-of-pulse detection **K242967 (Feb 2025)**.

Practical Takeaway: Clinician-in-the-loop diagnostic, triage, and screening AI SaMD routinely qualifies for **Basic Documentation** even under De Novo or PCCP. Expect **Enhanced Documentation** when software directly drives radiation dose, autonomous diagnosis without clinician confirmation, acute life-threatening alarms, surgical guidance, or contraception.

WHERE ENHANCED ACTUALLY TRIGGERS (ALL 27 MAPPED)

1. Radiation Therapy Contouring 7 of 27
100% of QKB/MUJ authorizations (7/7), matching FDA's **RT overdose/underdose example (p. 42)**. Illustrative: Varian AI Contouring **K261306 (Jul 2026)**, DeepBT **K252190 (Apr 2026)**, GE MR Contour DL **K242925 (Apr 2025)**, Limbus Contour **K241837 (Oct 2024)**, ART-Plan **K232479 (Dec 2023)**.

2. High-Acuity Cardiovascular & Sepsis 7 of 27
Matches FDA's **critical-care sepsis alarm example (p. 40)**. Illustrative: Sepsis ImmunoScore **DEN230036 (Apr 2024)** (cites that example directly), Queen of Hearts ACS ECG **DEN250044 (Sep 2026)**, Implicity ILR ECG **K253463 (Jul 2026)**, APPRAISE-HRI hemorrhage risk **K233249 (Apr 2024)**, plus EchoGo Amyloidosis & 2 DeepRhythmAI ECGs.

3. Autonomous Retinal Diagnostics (OP / PIB) 2 of 27
100% of PIB clearances (2/2), matching FDA's **AI retinal diagnostic example (p. 41)**: iPredict-DR **K253704 (Jul 2026)** and AEYE-DS **K240058 (Apr 2024)**.

4. Manufacturer Template / Voluntary Enhanced 8 of 27
7 Siemens Healthineers non-RT filings across syngo/MI lines use an Enhanced template, including the sole Enhanced CADt **K243145, syngo.CT LVO (Apr 2025)**, **K253786 (Jun 2026)**, and **K260055 (Sep 2026)**, while Siemens filed Basic on **K241770, Prostate MR AI (Mar 2025)**. Plus Softlink Imagine Enterprise Suite (Jan 2026).

5. Surgical Navigation & Contraception 3 of 27
Intraoperative ortho guidance: Zimmer Signature ONE **K260104 (Feb 2026)** and OrthoGrid Hip AI **K260077 (May 2026)**; plus digital birth control Natural Cycles **K253694 (Jul 2026)**.

WHAT THIS DOES NOT SHOW

- **Reporting is voluntary:** 510(k) summaries are not required to state documentation level. Of 687 post-June 14, 2023 AI/ML SaMD authorizations, 107 name Basic/Enhanced and 75 still cite legacy 2005 Level of Concern. Four recent AI SaMD De Novos (2025 to 2026) do not yet have published FDA decision summaries.
- **Risk-based, pre-mitigation test:** FDA evaluates documentation level on each device's specific hazards *before* software risk controls, not by product code or AI flag alone.
- **Voluntary over-documentation:** Sponsors with Enhanced-ready QMS templates occasionally submit Enhanced documentation when Basic would likely suffice (compare **radiological display example, p. 37**).

Sources: FDA Device Explorer by Innolitics (fda.innolitics.com), cohort of 687 AI/ML SaMD authorizations (Jun 14, 2023 to Nov 15, 2026; data as of Nov 17, 2026; pulled Nov 22, 2026); FDA Final Guidance *Content of Premarket Submissions for Device Software Functions* (Jun 14, 2023). Highlighted items link directly to source passages.