Supplementary Table S1: FDA approval pathways and sub-pathways for AI/ML-based devices

FDA regulatory pathway	Description
510(k) pathway	**Traditional 510(k):** depends on demonstration of Substantial Equivalence **Abbreviated 510(k):** depends on the use of guide documents, controls and recognized standards **Special 510(k):** when device modifications are made to a manufacturer's own legally marketed device
De Novo	**Option 1:** After obtaining a high-level not substantially equivalent (NSE) determination **Option 2:** After determining that there is no legally marketed device
Premarket approval (PMA)	**Traditional PMA:** include application with device description and intended use, nonclinical/clinical studies, case report forms, manufacturing methods, labeling **Modular PMA:** for medical products in early stages of clinical study **Product Development Protocol:** for devices that uses well established technology and serves as a contract upon details of design and development activities **Humanitarian Use Device (HUD): for** device intended to benefit not more than 8,000 patients in the treatment or diagnosis of a disease or condition

Supplementary Table S2: Primary product codes and related device classification

Primary Product Code	Device Classification Name
IYN	system, imaging, pulsed doppler, ultrasonic
JAK	system, x-ray, tomography, computed
LLZ	system, image processing, radiological
LNH	system, nuclear magnetic resonance imaging
MUJ	system, planning, radiation therapy treatment
QAS	radiological computer-assisted triage and notification software
QDQ	radiological computer assisted detection/diagnosis software for lesions suspicious for cancer
QFM	radiological computer-assisted prioritization software for lesions
QIH	automated radiological image processing software
QKB	radiological image processing software for radiation therapy