

## Case Law Analysis - AI Medical Device Cases

**Case law** related to AI medical devices serves as the foundation for **future regulations and liability interpretation**

### Key Dispute Cases

- **Misdiagnosis Liability:** Physician's diagnostic error following AI recommendations - Who is responsible?
- **Black Box Transparency:** Legal liability for unexplainable AI decisions
- **Data Bias:** Harm caused by poor performance in specific populations
- **Software Updates:** Accidents due to performance degradation after updates



### Precedent Analysis

Study of judgment patterns in similar cases



### Legal Doctrine Formation

Development of AI medical device-specific legal principles

### Risk Mitigation Strategies (Based on Case Law)

- **Clear Usage Guidelines:** Specify indications, limitations, and contraindications
- **Comprehensive Validation Documentation:** Performance evidence in diverse environments
- **User Training:** Appropriate training programs and completion certificates
- **Quality System:** Robust QMS and PMS operations



**Key Point:** While case law is still in its early stages, transparency, verifiability, and proper oversight are emerging as core elements of legal defense