

510(k) SUMMARY

K 964336

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Submitted by:

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Proprietary name: CMS AccuProbe® 610, 620, 630, 640, 650, 660, 670, 680

Common name: Cryosurgical Unit, Cryogenic Surgical Device or Cryoprobe

Classification: Cryosurgical unit with Liquid Nitrogen, Class II
[21 CFR § 878.4350(a)]

The CMS AccuProbe® 600 series consists of two components including: i) a console which holds three dewars of liquid nitrogen (LN₂) (one dewar is filled at a time; one dewar is a receptacle for the circulating LN₂ and the third dewar contains the super-cooling chamber); and ii) one to eight (models 610 through 680) cryoprobes with tips extending from the console. The console includes an optional on-board computer which is used as a redundant display system and an archival system to store information from the procedure. The computer does not control or affect the operation of the cryoprobes in any fashion. The cryoprobes consist of interchangeable tips of various materials, sizes and shapes to be utilized as necessary.

The device is used to destroy unwanted tissue by application of extreme cold to the selected site. LN₂ is forced through the cryoprobes under pressure. The cryoprobe, having been placed in the appropriate position through the use of ultrasound or another imaging device, then becomes cold and freezes the unwanted tissue. The procedure may be monitored in real-time through the use of imaging modes such as ultrasound. Once the freezing is completed (approximately 20 minutes) the probe will be heated using warm nitrogen gas in order to facilitate thawing and removal of the cryoprobe from the frozen tissue. The cryosurgical procedure is available when surgical resection is not possible and may also provide an alternative to typical resection in certain cases.

The CMS AccuProbe® 600 series is similar in form and function to the 550/530 AccuProbe®, being modified models of that device. The CMS AccuProbe® 550/530 was cleared for marketing in November 20, 1995. The intended use and principal of operation are the same.

COMPARISON OF FEATURES BETWEEN THE AccuProbe® 550/530 [CLEARED 510(k) (K953637)] AND THE AccuProbe® 600 SERIES

FEATURES	AccuProbe® 550/530	AccuProbe® 600 SERIES
Liquid Nitrogen Capacity (Dewar size)	85 liters	Model 610 15 liters Model 620 25 liters Model 630 40 liters Model 640 55 liters Model 650 70 liters Model 660 85 liters Model 670 100 liters Model 680 115 liters
Normal Operating Pressure	55psi	65psi
Regen time	four minutes	two minutes
Regen mode	Transfers the LN ₂ from the upper dewar to the lower (supply) dewar	Depressurizes the supply dewar and pressurizes the return dewar (this allows the capture of LN ₂ to flow from the return dewar through the cryoprobe back to the supply dewar)
Dimensions	54"x 29"x 47"	Model 610 45"x 24"x 29" Model 620 49"x 24"x 29" Model 630 52"x 24"x 29" Model 640 52"x 24"x 29" Model 650 54"x 28"x 32" Model 660 54"x 30"x 34" Model 670 54"x 32"x 34" Model 680 54"x 32"x 34"
Nitrogen Gas Supply	External Supply	Internally Generated