

APPROVED DEVICES

The following endoscopes meet the cleaning criteria cleared by the FDA under the cleaner mode of 510(k) K101158. As and when new endoscopes are introduced into the marketplace LIC will evaluate them and when appropriate validate them for use in the LIC cleaner. Those endoscopes will then be added to the list of cleared devices for processing in the LIC cleaner.

OLYMPUS MEDICAL

Bronchoscopes	Gastrosopes	Colonoscopes	Ultrasound
BF-P60	GIF-160	CF-Q160L	GF-UC-140P-AL5
BF-1T60	GIF-Q160	CF-Q160AL	GF-UCT-140-AL5
BF-1T160	GIF-XP160	PCF-160L	GF-UE160-AL5
BF-P160	GIF-1TQ160	CF-2T160L	GF-UM160
BF-MP160F	GIF-2T160	CF-Q180AL	GF-UCT160-OL5
BF-XT160	GIF-Q180	CF-H180AL	GF-UE160-AL5
BF-1T180	GIF-H180	CF-H180DL	TGF-UC180J
BF-1TQ180	GIF-H180J	PCF-Q180AL	GF-UCT180
BF-1T180	GIF-2TH180	PCF-H180AL	TJF-UC180J
BF-P180	GIF-XP190N	CF-HQ190L	Duodenoscopes
BF-Q180	GIF-H190	PCF-H190L	TJF-160VF
BF-1TH190	GIF-HQ190	PCF-H190DL	TJF-Q180V
BF-Q190	GIF-1TH190	PCF-PH190L	Sigmoidoscope
BF-P190	GIF-1TQ160	EBUS	CF-Q160S
BF-H190		BF-UC180F	

FUJINON MEDICAL

Bronchoscope	Colonoscopes	Duodenoscope
EB-530S	EC-530LS2	ED-530XT
EB-530H	EC-450BI5	EBUS
EB-530T	EC-530HL2	EB-530US
Gastrosopes	EC-530DL	Ultrasound
EG-530N	EC-600LS	EG-530UR2
EG-530NP	EC-600WL v2	EG-530UT2
EG-530WR	EC-600HL	
EG-530CT	EC-760R-V/ L	
EG-530D	Sigmoidoscope	
EG-600WR v2	ES-530WE	
EG-760R		

Post CRE breakout traced to duodenoscopes.

In an unprecedented action, LIC accepted the FDA recommendation of conducting further in-use testing with clinically used duodenoscopes and partnered with UCLA to conduct real-time cleaning evaluation of clinically used duodenoscopes in a normal clinical environment.

The UCLA evaluation confirmed that the cleaning operation of the LIC Instrument Processor when operated by health care personnel in a clinical environment consistently and reliably meets the cleanliness standard of $\leq 6.4 \mu\text{g}/\text{cm}^2$ protein established by the FDA.

The Duodenoscopes in the chart on the right were all cleaned under real world conditions at UCLA's Ronald Reagan Medical Center **without the benefit of manual cleaning assistance.**

PENTAX MEDICAL

Bronchoscope	Gastroscope	Colonoscope	Ultrasound	Sigmoidoscope
EB-1170K	EG-1690K	EC34 -i10L	EG-3270UK	ES-3870K
EB-1570K	EG-2990i	EC-2990Li	EG-3670URK	Duodenoscopes
EB-1575K	EG-2990K	EC-3490LK	EG-3870OUTK	ED-3490TK
EB-1970K	EG29 -i10	EC-3490LI	EBUS	ED-34110T
EB-1970TK	EG27 -i10	EC-3490TLI	EB-1970UK	
EB-1975K	EG-3490K	EC-3890LK	EB-19J10U	
	EG-3890TK	EC-3890LI		
		EC38 -i10L		
		EC-3890TLK		

CLEANED AT UCLA IN THE LIC
CLEANER

Duodenoscopes
Olympus TJF-Q180V
Olympus TJF-160F
Olympus TJF-160VF
Pentax ED-3490TK